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THE INFORMED CONSENT PROCESS IN PERCUTANEOUS CORONARY INTERVENTION: A COMPREHENSIVE SYSTEMATIC REVIEW

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ABSTRACT

Obtaining Informed consent is a fundamental aspect of ethical medical practice, and it is an important dialogue between the patient and the doctor. This procedure is particularly challenging in the case of Percutaneous Coronary Intervention (PCI), which is the most common method for treating coronary artery disease. The paper gives a systematic review of the available literature to understand how patients and cardiologists view the process of informed consent when it comes to PCI. The review examines 14 studies that are relevant to the subject area and finds that there is an important theme of insufficient education to patients regarding the ethical and legal aspects of their consent. In many cases, patients are excessive on the advantages of PCI and ignore risks and other treatment options. In addition, physicians often hurry the process or fail to explain the process properly, thus creating a knowledge gap between patients. The results strongly show that the process of making decisions is not always a team undertaking. This review concludes that informed consent to PCI must be redefined as an interactive, continuous process and not as an administrative formalism, in which the autonomy and understanding of patients are given the priority in cardiac treatment.

Keywords: informed consent, percutaneous coronary intervention, cardiologists, patient communication, shared decision-making, medical ethics

1. INTRODUCTION

Informed consent is much more than a signature on a piece of paper and is an intrinsic ethical and legal principle which upholds patient autonomy and gives people the right to make voluntary choices concerning their healthcare. In sensitive medical operations such as Percutaneous Coronary Intervention (PCI), which is a life-saving intervention in blocked arteries of the heart, a strong consent procedure is the key. Although it is a standard procedure, it is associated with complications, and it is not the only possible treatment plan for coronary artery disease. The therapeutic model of care does not only concentrate on the technical achievement of the procedure but the whole patient's experience, which begins with a clear idea of what the intervention involves.

Cardiovascular diseases (CVDs) continue to be the major cause of death in the world. These disorders impact on the heart and blood vessels and tend to be caused by atherosclerosis, which is the deposition of fatty plaques in the arteries. This constriction may cause coronary artery disease (CAD) in which vessels that transport rich oxygen blood to the heart muscle are impaired. A heart attack (myocardial infarction, MI) may develop in case of a serious decrease or clots in the blood flow. According to American Heart Association (2020), hundreds of thousands of Americans have a first heart attack annually, whereas British Heart Foundation (2018) claims that it is one of the main causes of hospitalization in the UK[1 2].

PCI has become a major treatment of acute MIs and stable CAD. It involves low-invasive surgery to open constricted or obstructed coronary arteries and may include placement of a stent to hold the vessel open. Nevertheless, the time-consciousness of the situation, especially in acute cases, as well as the complexity of information makes the process of informed consent a great challenge. This paper aims to conduct a comprehensive and systematic survey of the difficulties inherent in the informed consent process for PCI, synthesizing the experiences and views of both patients and doctors to identify key problems and propose avenues for improvement.

2. UNDERSTANDING THE CLINICAL CONTEXT: HEART DISEASE AND PCI

Informed consent in PCI is a concept that is best appreciated by first comprehending the clinical background. Cardiovascular diseases refer to a cluster of heart and blood vessel diseases. A particular form of CVD is called Coronary Artery Disease and it occurs when the major blood vessels which supply the heart are damaged or diseased. This is most often due to the deposition of cholesterol-bearing (plaque) and inflammatory deposits.

A rupture of a plaque may result in the formation of a blood clot at the location that may completely block the circulation of blood. This incites a myocardial infarction. The heart muscle becomes starved and dies out of lack of oxygen and nutrients. This is a medical emergency. Depending on the results of the electrocardiogram (ECG), myocardial infarctions are categorized; non-, ST-elevation myocardial infarction (STEMI) is a symptom of an absolute blockage of a coronary artery and is treated immediately.

The most effective and standard treatment of STEMI is Primary Percutaneous Coronary Intervention (PPCI). This aims at restoring blood supply to the heart muscle within the shortest time possible to minimize permanent harm. The European Society of Cardiology (2018) recommends that it should be fast, and the time taken between initial medical contact and opening the artery should not exceed 90 minutes.[3] Fibrinolytic therapy (so-called clot-busting drugs) can also be applied in cases when a hospital with PCI capabilities is not immediately available, but this is fraught with risks, including intracranial bleeding. [4]

Percutaneous Coronary Intervention (also called angioplasty in the past) is a procedure where a fine catheter is inserted into a blood vessel and then directed to the blocked artery in the heart. A small balloon is inflated to squeeze the plaque against the walls of the arteries, and a stent is usually placed to scaffold the artery. First introduced by Andreas Gruentzig in 1977, PCI has come to the point of being a highly advanced life-saving surgery. [5]

While highly successful, PCI is not without risk. In-hospital mortality rates vary, being lower for elective procedures (around 0.2%-0.65%) and higher for emergency cases like STEMI (ranging from 4.6% to 7.4%). [6 7] Factors such as age, sex, and comorbidities like diabetes can influence these outcomes. It is precisely these benefits, risks, and alternatives that form the core of the information that must be communicated during the informed consent process.

3. THE EVOLUTION AND PRINCIPLE OF INFORMED CONSENT

The history of informed consent is complex. The medical world of the 1950s was significantly paternalistic. The principle of the first, do no harm, was occasionally applied to deny distressing information to patients and physicians make choices on behalf of patients, thinking that it was in their best interest. [8] There was a lot of minimal truth-telling which was hesitant.

This paradigm started changing and the first formal guidelines on informed consent were established in 1978, mostly due to an understanding that it was necessary to fully reveal risks and benefits. According to Paterick et al. (2008) medical informed consent became an important aspect of the work-related tasks of the physician and turned into a real form of partnership between the physician and the patient and the latter sharing the rights and responsibilities of the outcomes of the treatment [9].

Informed consent is accepted today as legal and ethical. It is the process of a medical practitioner informing a patient about what a planned treatment or procedure entails, its possible advantages, its material risks, and viable options, as well as the costs of not treating. Trust and this decision-making process are achieved through effective communication. Put simply, it is a process that is necessary to make sure that the patient is knowledgeable about their situation and the intervention offered. [10]

Various conditions must be satisfied to be considered as consent valid: the patient should be able to make the choice, should not be forced to make the choice and should be informed enough. This usually leads to the conclusion by signing a document which will be used as a witness that the conversation has occurred and the patient agrees. This piece is however not the consent itself; it is only the account of the same; the actual consent is the act of communication and comprehension.

4. METHODOLOGY

This article is based on a systematic literature review designed to comprehensively gather and synthesize existing research on the informed consent process in PCI.

4.1. Aims and Search Strategy

The primary aim was to investigate the views of both patients and cardiologists on the informed consent process for PCI. A structured search was conducted using the PEO framework (Population, Experience, Outcome) to guide the inquiry. The population included patients undergoing elective or emergency PCI and the cardiologists treating them.

4.2. Inclusion and Exclusion Criteria

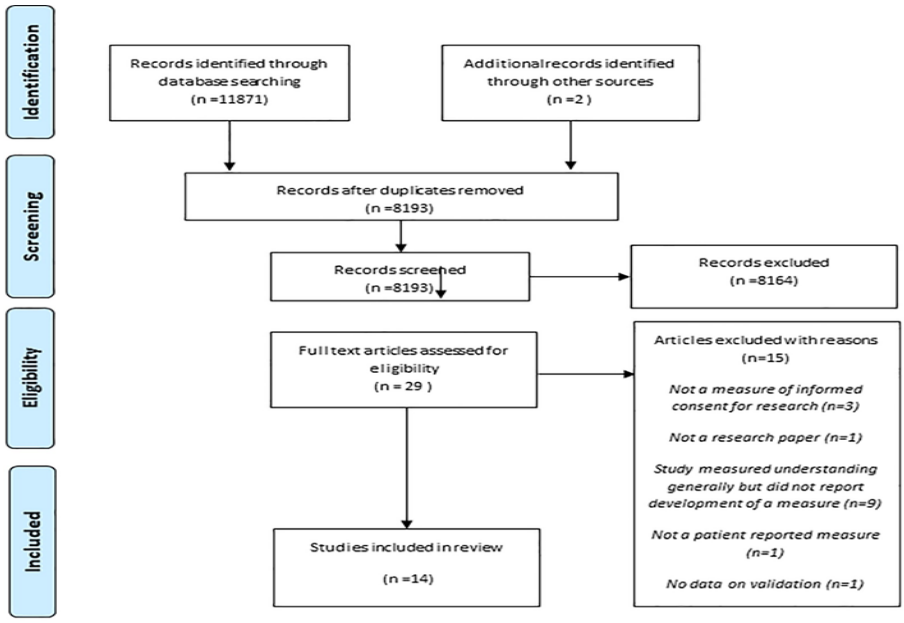
Table 1: Inclusion and Exclusion criteria

Criteria	Inclusion criteria	Exclusion criteria
Population	Patients that have elective or emergency PCI Cardiologists	Below 18 years
Experience	Informed consent in percutaneous Coronary intervention	Informed consent for participation in research trials
Outcome	Experience Views opinions	
Research time frame	2010-2022	Previous studies before 2010
Type of study	Both qualitative and quantitative studies will be used Peer-reviewed articles	Commentary case studies

4.3. Data Sources and Extraction

The research group gathered data from four primary electronic databases, namely, PubMed, Medline, Cochrane Library, and CINAHL Complete. The databases were selected according to their vast coverage of literature in the fields of biomedicine and nursing. The search strategy was a combination of free-text words and controlled vocabulary terms, along with the application of Boolean operators ("AND", "OR") for the purpose of narrowing down the output. A total of 8,192 articles appeared because of the first search. After a thorough scrutiny of the titles and abstracts, 29 full-text literatures were considered for eligibility from which 14 studies that fulfilled all the criteria were chosen for the final synthesis. To reduce mistakes and ensure uniformity in collecting significant information from each study, a common data extraction template was applied.

5. KEY FINDINGS



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

Figure 1: Prisma flow chart

The synthesis of the 14 included studies revealed several consistent and concerning themes, highlighting a significant disconnect between the ideal of informed consent and the reality experienced by many patients and clinicians.

Table 2: Summary of the 14 Included Studies

Study (Author, Year)	Number of Participants	Average Age/Range (years)	Location	Interventions	Outcomes Measured	Assessment Used
Astin et al. (2020)[11]	118 cardiologists, 326 patients	England	England	PCI	Understanding of treatment benefits; Views on consent process	Cross-sectional surveys
Blanchard et al. (2020)[12]	82	Single academic medical centre, US	United States	PCI	Patient perspective of the informed consent process	Exploratory descriptive study
Dathari et al. (2014)[13]	102	Not reported	Not reported	Elective PCI	Successful identification of all PCI risks	Questionnaires
Goff et al. (2014)[14]	Not reported	64	Not reported	Angiogram and PCI	How cardiologists present the benefits of PCI	Qualitative content analysis
Howard et al. (2014)[15]	82	65	Not reported	PCI	How healthcare providers can improve informed consent	Qualitative study (Survey)
Kureshi et al. (2014)[16]	991	US academic and community hospital	3 sites	Elective PCI	Patients' perceptions of the urgency and benefits of PCI	Interviews
Larobina et al. (2007)[17]	90	62 (PCI), 68 (CABG)	Single tertiary hospital, Australia	PCI and CABG (Elective and non-elective)	Expected treatment benefits and alternatives offered	Interviews and questionnaires
Lee et al. (2012)[18]	347	69	Two city hospitals, USA	Elective PCI	Patient understanding of intervention (expected benefits and alternatives)	Not reported
Probyn et al. (2017)[19]	Not reported	England	Northern England	Elective and Acute PCI	Patients' and cardiologists' experiences of the informed consent process	Interviews
Rothberg et al. (2010)[20]	180	Academic setting	Not reported	Elective coronary catheterization and PCI	Patients' and cardiologists' beliefs about benefits of PCI	Survey

Spatz et al. (2016)[21]	Not reported	UK	Not reported	Informed Consent	The need for a reasonable-patient standard through shared decision making	Survey / Commentary
Spertus et al. (2015)[22]	1117	US centers	Not reported	PCI	Impact of a personalized consent document on the informed consent process	Survey

Numerous research papers have indicated that during the waiting period for a PCI (percutaneous coronary intervention) procedure, the patients often do not get the complete or unbiased information. [23] The method of delivering the information is sometimes non-uniform and one-sided. The medical practitioners may accentuate the advantages of the procedure but talk very little about the hazards or other treatment options available. Consequently, patients, in most cases, assume that PCI would stop heart attacks from occurring or at least lessen their chances of dying, notwithstanding the fact that research has revealed this is not always the case with patients having stable heart conditions. [24] This misconception results in a situation where, unknowingly, many patients give their consent for the treatment without understanding what it will and what it will not do for them. They could be expecting only the good things to happen and might also be ignoring the possible bad ones or the fact that the treatment might also help them to cope with their illness as quickly as the medicine[25].

The knowledge deficiency is due to many factors. The major one is time. Cardiologists are often employed in the outpatient departments of hospitals and think that they do not have sufficient time to explain the whole thing with kind details. They might even practice the consent process hurriedly, in their way, during emergency cases. A further factor is that the information is itself complicated and full of medical terminology that the patients do not comprehend. The use of jargon and complex explanations can overwhelm the patients and consequently make them feel confused or lost. When patients are not provided with clear information, it is possible that they cannot remember or fully understand what is being said.

Patient characteristics are also among the factors that influence the understanding and involvement of the patient in the consent process. Many individuals who are informed that a heart procedure might be necessary experience anxiety, freight, or stress. The emotional burden in the form of vices makes it so hard to digest complex information and to formulate good questions. When a person is scared, he or she might just concur with whatever the physician proposes merely to finish it off. Some patients even arrive at the hospital already convinced that PCI is the only way to treat their heart problem [26]. They may have such a viewpoint because of what they have been told by relatives, friends, or the media. The latter often present surgery as the most potent or effective solution. If a patient is already of this opinion, he or she is probably not going to pay close attention during the doctor's explanation of the risks or his or her mention of alternative treatments.

Different patients also vary in the extent of their information needs. Some are keen to catch every detail, to be told of all the uncertainties as well, and to have a major say in the decision. Others do not want to know everything, as it would make them anxious, and they would rather give the doctor their complete trust. Thus, applying a single strategy to all patients will not be very effective. Physicians are required to identify the needs of every single patient and then to customize the explanation in a manner that the patient feels are both respectful and helpful. [27]

The process of acquiring consent is communication-dependent and at the same time one of the greatest challenges. When talking to the doctors, the patients are really expecting nothing less than communication that is straight and simple. In the scenario where the doctors must resort to medical vocabulary, the patients not only feel confused but also at times frightened. Jargon can create a wall between the patient and the doctor instead of breaking the wall down. The patients are less likely to be curious and ask any questions. Many patients do complain about certain cardiologists such as speaking fast, interrupting, and judging the patient as if he/she knows much about the procedure. This one-way communication style generally leads the patients to the conclusion that their feelings and thoughts do not matter. On the other hand, a cardiologist who realizes the patient's needs and adopts a patient-centered approach is the one who proves effective in calming the patient through speaking slowly, understanding checking, and showing empathy. [28] A few doctors utilize the "teach-back" technique wherein they allow the patients to narrate in their own words what they think they have understood. Although very simple, this powerful technique assures that the patient is aware of what will happen

next. The trustful relationship with the patient will be built through the doctors who are tender with the patients and offer concern and even use humor. These are the ones who will be successful in overpowering the patient's fear and creating a bond of trust.

On the other hand, there is another factor that influences communication—the concept of the "ideal patient." Many individuals consider that a good patient is the one who is silent, agreeable, and will not trouble the doctor with numerous questions. They are scared that by asking questions, they will be categorized as difficult or that they will be taking the doctor's time. This bad idea gets even stronger in environment of a busy hospital where a doctor's interaction with a patient is just a few minutes and always appears very rushed. As a result, patients sometimes do not voice their concerns even when they realize that they miss the understanding of the most crucial points. Thus, they sign the consents and give the go-ahead for the surgeries without really being sure of their choice. [29] [31]

The relationship of trust between a doctor and a patient is very important, but, on the other hand, it can also lead to problems when it becomes too strong. A lot of patients put their doctors on a very high pedestal and think that any treatment the doctor prescribes must be the best decision. Such patients might even start to develop a habit of not thinking for themselves or of not asking the doctor to explain anything. For some people, putting the decision in the hands of the doctor is like the safest and the most comfortable thing to do since they consider themselves to be lacking the necessary knowledge for making the decision for themselves. The case of emergency does escalate this trust and reliance. When a person is in pain or panic, he/she might see the doctor's advice as the only, and hence, the best course of action. In such instances, informed consent may be little more than a formality than a genuine choice.

The presence of family and friends to the patient's decision-making process has a great influence on how the patient will make the decision. Plenty of patients consult with their nearest and dearest, before giving their consent to treatment, to receive advice and comfort. Such discussions between patients and their families can be advantageous, but at the same time, they may cause the patients to feel pressured. For instance, if a relative is convinced that PCI is the best option, then, the patient might feel obliged to concur even if he/she has some reservations. Moreover, the very notion of a real choice is often a mirage. [30] Numerous patients think they are making a choice, but the truth is that they feel that PCI is the only option allowed. This feeling of having "no real choice" is further consolidated when doctors do not thoroughly inform patients about other treatment possibilities or when alternatives are presented as less desirable. Patients in this condition might think that the decision has already been made for them and therefore will just go with what the doctor suggests.

The opinions of the cardiologists also shed some light on the weak points in the consent process. Some doctors, seeing it as a regulation rather than ethical talk, have a hard time wrapping their minds around its necessity. They treat it as a legal issue that is better avoided and not as a means to empower the patients with the right information. Hence, the cases of consent are seen as inevitable and automatic rather than substantial. The divided hospital care is another factor that complicates the situation. Typically, the doctor who explains the procedure and secures the patient's consent is different from the one who performs the surgery. The cardiologist saw the patient on the day of surgery, but the consent form had already been signed. It is not very long to either trust the patient or assess the patient's understanding of the procedure that is going to happen. The cardiologist might only check if the patient has "no more questions" and proceed, assuming that the previous conversation was sufficient.

This fragmentation is harmful to the doctor-patient bond. Genuine shared decision-making needs the factors of care, and patience for compassion and dialogue. Such a consent process is simply lifeless. The patients put their signature on the papers without getting a full understanding of their choices, while the doctors presume to have fulfilled their legal duty, though not necessarily their ethical one.

6. DISCUSSION

The results of the review depict vividly the situation. In most instances, the present informing consent for PCI is not up to the mark of the ethical and legal standards. Rather, the procedure is viewed as just writing a name on a piece of paper—than as an interactive and continuous process of communication and decision-making.

The main concern is systemic, which emanates from a blending of factors such as time pressure, complicated information, different patient preferences and abilities, and, at times, a medical culture that has not yet fully embraced shared decision-making. The disparity in knowledge is not merely about patients misremembering details; it is often the consequence of biased and incomplete disclosure right from the start. [31] If patients are not informed that PCI for stable angina may not prevent

heart attacks or increase survival, but is mainly for comfort, then they are not able to give a genuinely informed choice.

The trust issue is of utmost importance. Trust is the bedrock of the physician-patient relationship while at the same time the consent process must ensure that the trust is not blind. A patient's decision to relinquish the decision-making power to their doctor should be an informed one, done with an acknowledgment of what they are relinquishing. [32] The existing procedure does not often make this distinction, hence there are instances where patients consent to treatments based on unrecognized benefits.

Elected and emergency settings' differences make the issue more intricate. In the case of acute STEMI, time for lengthy discussion is not available. [33] The main goal is to preserve the heart muscle and life. In such situations, the process might rightly be truncated to verbal consent. Nevertheless, for non-emergency procedures, there is no justification for hasty or partial consent process. This is where major improvements can and should be made. [34]

The results are also a direct hit against the conventional paternalistic mode of healthcare. The circumstance of patients having differing preferences regarding information does not bridge nor mitigate the responsibility of doctors to say the least about the important information. Communication should be done according to the patient and not the other side where the topic is reduced. [35] Core information sets, which are standardized and evidence-based lists of the most significant risks, advantages, and alternatives, can be employed, thereby guaranteeing that all the patients are given a certain minimum of essential information, which can later, if required, be enlarged or reduced depending on their wants and needs. [36]

Drawn from the limitations, the review findings are still a valuable source of lessons for health care practice. The most important one is that the consent process should be redesigned to turn into a more patient-centered and meaningful one. The first thing is that the consent should not be put into a single event occurring right before the procedure. On the contrary, it should be a continuous process starting when the patient first gets a referral for PCI. Which allows the patients to have time for systematically thinking, talking with their family, and preparing their questions. The second point is that decision aids must be applied in the process of understanding the procedure. One way this could happen is by providing a very simplistic and clear introduction to PCI, its risks and the medication-based therapy among others, and the explaining of what the procedure is in very simple terms. [34 37] Another area to focus on is communication among doctors, nurses and patients, which should be the case. Healthcare professionals would have to undergo communication and shared decision training to be able to translate medical info accurately and ascertain patient's comprehension. [38] Most frequently "teach-back" method is considered the best and most convenient way in such a case where patients can paraphrase and express in their own words what they have heard or learnt. Cardiologists should not, however, be quick to judge when a patient expresses an uncertainty in the effectiveness of the procedure, or whether the PCI would prevent future heart attacks or mortality in a patient with stable coronary artery disease, for instance. [39] By nature of their medical skills, doctors can steer patients to make calm and well-grounded choices if they are open-minded and truthful about what PCI can and cannot do. Simply put, the consent would have to cater to the different patient's preferences around and also be flexible enough to accommodate them. [40] While some patients prefer to be fully informed and actively involved, others will prefer to rely on the doctor's discretion. The good consent process should not only respect these variations but also ensure that all ethical and legal requirements for full disclosure are met.

Future research can take many different paths that are based on what already is known. One of the major issues is to propose various methods and then put them into real-world situations to find out which method for obtaining consent is the most effective. For example, the researchers can come up with a range of decision-support tools or forms and measure the effect of these tools on the patient's understanding, satisfaction, and trust in their decision. Such an impact evaluation would be very essential for confirming the real winners concerning practice. [35] In addition, scientists may want to consider conducting a cross-cultural comparison on how patients who come from different cultural, educational, and linguistic backgrounds experience consent. The difference in people's comprehension and expectations might be so significant that it would still be important to ensure that the process is fair and accessible to all, regardless of their background.

Also, it can be argued that researchers should direct their focus more on the referral stage where a lot of investigations regarding PCI are done. The patient is not yet presented to the interventional cardiologist then, but still, a lot of decisions are being made. It can be that understanding what is happening at this stage will reflect the whole

treatment pathway communication where very early in the treatment improvement is done. In the end, weighing the consent practices in different countries, varying healthcare systems, and even different clinical environments like emergency versus planned procedures may lead to the identification of models producing the best patient outcomes. Thus, through exposure to various systems and approaches, healthcare organizations would be able to develop better and more uniform ways of supporting informed consent.

9. CONCLUSION

The obtaining of informed consent for Percutaneous Coronary Intervention is a very complicated and lengthy process which involves various factors, and even so, it is not everywhere in the clinical field at its best. The systematic review alludes to a patient-centered approach that has by no means been completely achieved since patients are more knowledgeable about the good effects and less knowledgeable about the bad and the other possible options. The main barriers to the process are time limitations, communication difficulties, anxious patients, and a general tendency in the system to regard consent as a legal ritual rather than an ethical dialogue.

The whole situation demands a change of strategy. The informed consent process should be set up as a continuous constructive dialogue where the exchange of views is the norm instead of being the exception. Communication that benefits patients, provision of specialized information, and new decision-support tools are among the factors involved. Time, training, and resources would also be necessary for the clinicians to conduct the process properly as it demands. The medical community can not only make the PCI pathway technically effective but also ethically sound by placing patient understanding and autonomy at the forefront, thus upholding the universal principle that every patient has the right to make an informed choice regarding their lives and bodies.

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DISCLOSURE STATEMENT (CONFLICT OF INTEREST)

The author reports that there are no competing interests to declare.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

DATA DEPOSITION STATEMENT

No primary data were generated or deposited as part of this systematic review.

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