Quality of Cardiovascular Shared Decision-Making Aids Based on IPDAS 4.0 Standards: A Systematic Review (Postprint)

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Abstract

Background Cardiovascular disease (CVD) poses a serious threat to the life and health of residents, and the effectiveness of its prevention and treatment largely depends on scientific and rational medical decision-making. With the development of the shared decision-making (SDM) model, patient decision aids (PDAs) have gradually become an important tool for promoting physician-patient communication and enhancing patient engagement. However, the current development quality of PDAs in the cardiovascular domain is uneven and lacks unified standards. The International Patient Decision Aid Standards (IPDAS 4.0) provides an evidence-based framework for the content design and effectiveness evaluation of PDAs. This study performs a systematic evaluation of PDAs in the cardiovascular field based on the IPDAS 4.0 criteria, aiming to provide evidence for clinical practice.

Objective To evaluate the effectiveness of PDAs in the application of SDM among patients with CVD.

Methods We systematically searched PubMed, Embase, Web of Science, Cochrane Library, CNKI, VIP, Chinese Biomedical Literature Database, and Wanfang Data Knowledge Service Platform for randomized controlled trials investigating the effectiveness of PDAs in patients with CVD, with the search timeframe spanning from database inception to October 31, 2023. Two investigators independently screened the literature, extracted data, and assessed the quality of included studies. The intervention group received PDA interventions in various formats, while the control group received usual care. The development quality of PDAs was evaluated using IPDAS 4.0, and meta-analysis was performed using RevMan 5.4 software.

Results A total of 16 studies comprising 4,861 patients were included. IPDAS

4.0 evaluation revealed that the three highest-scoring themes were conflict of interest declaration, health problem and option information, and information on patient values, while the three lowest-scoring themes were testing, plain language, and evaluation. Meta-analysis demonstrated that compared with the control group, the intervention group significantly improved patients' knowledge level [SMD=0.88, 95%CI (0.52~1.24), P<0.001] and reduced decisional conflict [SMD=-0.21, 95%CI (-0.40~-0.03), P<0.001], specifically in the dimensions of informed [SMD=-0.36, 95%CI (-0.48~-0.25), P<0.001], values clarification [SMD=-0.24, 95%CI (-0.35~-0.13), P<0.001], support [SMD=-0.19, 95%CI (-0.31~-0.08), P<0.001], and effective decision [SMD=-0.20, 95%CI (-0.31~-0.08), P<0.001].

Conclusion PDA intervention is effective in reducing decisional conflict, improving decision satisfaction, and enhancing knowledge levels, but its impact on reducing patients' decision regret requires further investigation. Future efforts should focus on developing high-quality PDAs for the CVD domain based on IPDAS 4.0, tailored to China' s healthcare context, to facilitate the implementation of SDM in clinical practice.

Full Text

Systematic Review of Patient Decision Aids in Cardiovascular Disease Based on IPDAS 4.0 Criteria

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Abstract

Background: Cardiovascular disease (CVD) is a major threat to human health, and its prevention and treatment largely depend on evidence-based and rational medical decision-making. With the development of the shared decision-making (SDM) model, patient decision aids (PDAs) have increasingly been used to facilitate clinician-patient communication and enhance patient engagement in decision-making. However, the quality of cardiovascular PDAs varies considerably and lacks standardized regulation. The International Patient Decision Aid Standards (IPDAS 4.0) provide an evidence-based framework for the design and evaluation of PDAs. This study systematically evaluated PDAs in the cardiovascular field using the IPDAS 4.0 framework to provide evidence for clinical practice.

Objective: To evaluate the effectiveness of PDAs in SDM among CVD patients.

Methods: A systematic search was conducted in PubMed, Embase, Web of Science, Cochrane Library, CNKI, VIP, CBM, and Wanfang Data, covering publications up to October 31, 2023. Randomized controlled trials (RCTs) evaluating the effects of PDAs in patients with CVD were included. Two researchers independently screened the studies, extracted data, and assessed methodological quality. Intervention groups received PDAs in any format, while control groups received routine treatment or care. The quality of PDA development was assessed using IPDAS 4.0, and meta-analysis was performed with RevMan 5.4.

Results: A total of 16 RCTs involving 4,861 patients were included. According to IPDAS 4.0, the three highest-scoring domains were disclosure, information, and values, while the three lowest-scoring domains were test, plain language, and decision support technology evaluation. Meta-analysis indicated that PDAs significantly improved patients' knowledge [SMD=0.88, 95%CI (0.52-1.24), P<0.001] and reduced decisional conflict [SMD=-0.21, 95%CI (-0.40–0.03), P<0.001]. Reductions in decisional conflict were observed across the informed [SMD=-0.36, 95%CI (-0.48–0.25), P<0.001], values clarity [SMD=-0.24, 95%CI (-0.35–0.13), P<0.001], support [SMD=-0.19, 95%CI (-0.31–0.08), P<0.001], and effective decision [SMD=-0.20, 95%CI (-0.31–0.08), P<0.001] subscales.

Conclusion: PDA interventions are effective in improving knowledge, decisional satisfaction, and reducing decisional conflict among CVD patients, though their impact on decision regret requires further investigation. Future studies should integrate China' s healthcare context to develop PDAs tailored to CVD patients based on the IPDAS 4.0 framework, thereby promoting the implementation of SDM in clinical practice.

Keywords: Cardiovascular diseases; Decision making, shared; International Patient Decision Aid Standards; Decisional conflict; Meta-analysis

Introduction

Cardiovascular disease (CVD) is the leading cause of death globally [1] and ranks first among causes of death in urban and rural residents in China, with its incidence and mortality continuing to rise annually [2]. Since clinical decision-making for CVD involves multiple options with comparable advantages and disadvantages [3-4], patients often struggle to make timely decisions aligned with their personal values and preferences. The current medical decision-making paradigm is shifting from paternalistic or informed decision-making toward shared decision-making (SDM) [5]. SDM facilitates collaborative, bidirectional knowledge and information exchange between healthcare providers and patients through patient decision aids (PDAs) to reach consensus on diagnosis and treatment [6]. PDAs are evidence-based tools that provide information on the risks and benefits of treatment options, helping patients consider and clarify their values and preferences, participate in the decision-making process, make informed

choices, and reduce decisional conflict [7]. In recent years, the number and types of cardiovascular PDAs have grown substantially and gained widespread clinical application, yet their development quality has not received sufficient attention from researchers [8]. The International Patient Decision Aid Standards (IPDAS), first published in 2003 and updated to version 4.0 in 2014 through a Delphi process involving 122 experts from 14 countries [9], serve as an evidence-based framework for standardizing PDA content, development, implementation, and evaluation. Therefore, this study evaluated the development quality of cardiovascular PDAs according to IPDAS 4.0 and conducted a meta-analysis of their application effects to provide evidence for improving informed decision-making among patients in clinical practice.

Methods

Search Strategy

We systematically searched PubMed, Embase, Web of Science, Cochrane Library, CNKI, VIP, CBM, and Wanfang Data from inception to October 31, 2023. A combination of subject headings and free-text terms was used. Chinese search terms included "shared decision-making/decision aid/decision support" AND "heart disease/cardiovascular disease/coronary heart disease/heart failure/atrial fibrillation/valvular heart disease/myocardial infarction/arrhythmia/cardiac insufficiency." The PubMed search strategy is detailed in Table 1 .

Study Selection

Inclusion Criteria: We included RCTs evaluating PDAs in adult patients with CVD (including coronary heart disease, heart failure, arrhythmia, etc.) facing medical decisions. The intervention group received PDAs in any format, while the control group received routine treatment or care.

Exclusion Criteria: (1) Duplicate publications (only the most comprehensive one retained); (2) Reviews or conference abstracts; (3) Studies with unavailable full text or missing data; (4) Studies with quality grade C; (5) Studies not meeting IPDAS 4.0 qualification criteria.

Two researchers independently screened literature, extracted data, and cross-checked results. Disagreements were resolved through discussion with a third researcher. Extracted data included author, publication year, country, sample size, mean age or age range, decision question, PDA type and content, intervention measures, and outcome indicators.

Risk of Bias Assessment

We used the Cochrane Handbook for Systematic Reviews of Interventions (version 5.1) to assess risk of bias, evaluating random sequence generation, allocation concealment, blinding, completeness of outcome data, selective reporting, and other sources of bias. Studies meeting all criteria were graded as A; those

partially meeting criteria as B; and those not meeting criteria as C (excluded). Given the difficulty of blinding in clinical trials on decision-making participation, studies without double-blinding but meeting other criteria were graded as B.

PDAs Quality Evaluation

IPDAS 4.0 comprises 44 items categorized into three domains: (1) Qualification criteria (6 items) defining essential PDA characteristics; (2) Certification criteria (10 items) minimizing risk of harmful bias; and (3) Quality criteria (28 items) representing optimal standards. The last 4 certification items and last 5 quality criteria are specific to test PDAs. All items can be grouped into 10 themes: health problem and options information, probabilities information, patient values information, decision guidance, development process, evidence references, conflict of interest disclosure, plain language, evaluation, and test-specific criteria. Each item is scored 1-4 (1=strongly disagree, 4=strongly agree), with scores $ $3 considered acceptable. The maximum total score is 176.

Statistical Analysis

We performed meta-analysis using RevMan 5.4. For continuous outcomes measured with identical methods and units, we used weighted mean difference (MD) with 95% confidence intervals (CI); otherwise, we used standardized mean difference (SMD) with 95% CI. Heterogeneity was assessed using ^{2} tests and I^2 statistics. If P$ $0.1 and $I^{\{2\}\$\$\ 50}\{2\}\$>50\%$, indicating heterogeneity, we used a random-effects model with sensitivity analysis, subgroup analysis, or descriptive analysis. Statistical significance was set at $P<0.05$.

Results

Literature Search Results

The search yielded 7,556 records. After removing 2,996 duplicates using EndNote, we screened 4,560 titles and abstracts, excluding 4,493 irrelevant studies and retaining 67 for full-text review. Ultimately, 16 English-language RCTs were included. The PRISMA flow diagram is shown in Figure 1

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Characteristics and Methodological Quality of Included Studies

The 16 included PDAs [11-26] involved 4,861 patients (2,416 in intervention groups, 2,445 in control groups). Ten studies [12,14,16,20-26] described randomization methods and implemented allocation concealment; two [14,20] blinded participants and interventionists; three [21,22,25] blinded outcome assessors; 14 [11-13,15-17,19-26] had low risk of selective reporting; and eight [11-13,16,20,22-23,25] used intention-to-treat analysis. Overall quality was good: three studies [21-22,25] were grade A, and the remainder were grade B. Cardiovascular PDAs

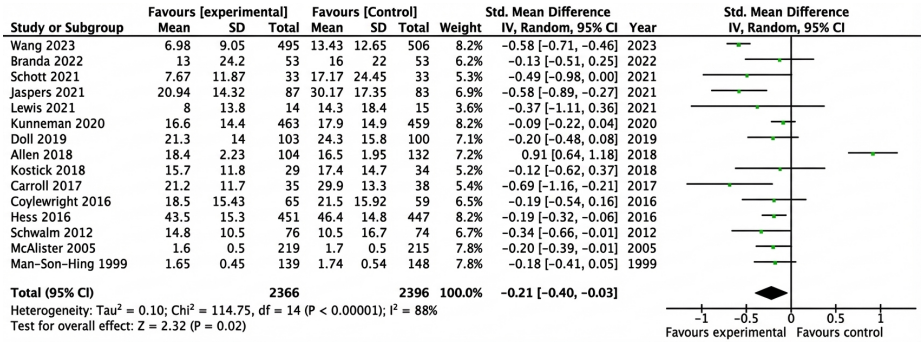

Figure 1: Figure 1

primarily addressed coronary artery disease, atrial fibrillation anticoagulation, and cardiac device implantation, covering disease knowledge, treatment options' pros and cons, personal risk assessment, and patient experiences. Study characteristics and quality assessment results are summarized in Table 2 .

Quality Evaluation of Included PDAs

All PDAs met qualification criteria but scored lower on certification and quality criteria. The mean IPDAS 4.0 total score was 120.1 (range 103-135) out of 176. The highest-scoring themes were: (7) conflict of interest disclosure, (1) health problem and options information, and (3) patient values information. The lowest-scoring themes were: (10) test-specific criteria, (8) plain language, and (9) evaluation. Detailed quality evaluation results are presented in Table 3 .

Meta-Analysis Results

Decisional Conflict Fifteen PDAs [11-17,19-26] evaluated decisional conflict. Due to significant heterogeneity (I^2=88%, P=0.02), we used a random-effects model. Results showed PDAs significantly reduced decisional conflict compared to usual care (SMD=-0.21, 95%CI -0.40 to -0.03, P<0.001)

. One study [18] not included in the meta-analysis also reported that PDAs helped patients make more informed choices, thereby reducing decisional conflict and promoting SDM.

Eight studies [14-15,20-21,23-26] used the Decisional Conflict Scale (DCS), which comprises five subscales: informed, values clarity, support, effective decision, and uncertainty [27]. No heterogeneity was observed among these studies, so we used a fixed-effects model. PDAs significantly reduced conflict in the informed (SMD=-0.36, 95%CI -0.48 to -0.25, P<0.001) [FIGURE:3], values clarity (SMD=-0.24, 95%CI -0.35 to -0.13, P<0.001)

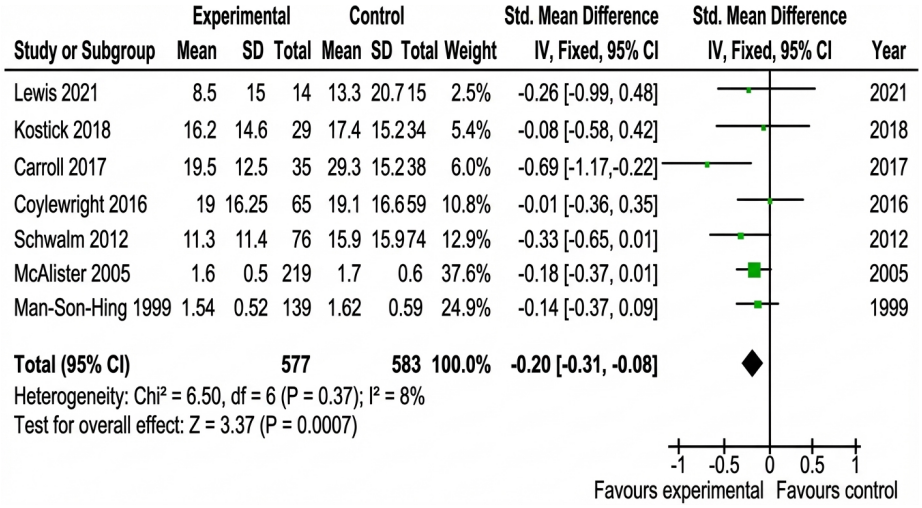

Figure 2: Figure 2

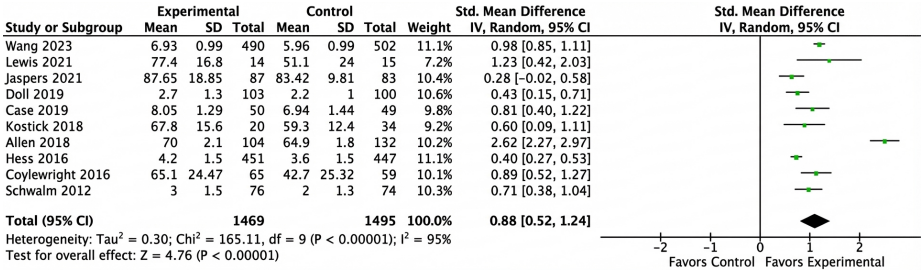

Figure 3: Figure 4

, support (SMD=-0.19, 95%CI -0.31 to -0.08, P<0.001)

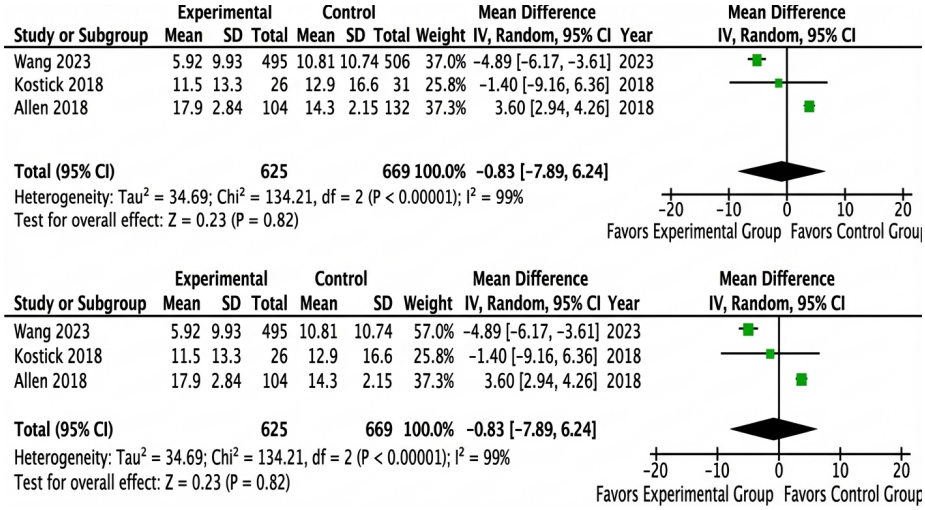

Figure 4: Figure 5

, and effective decision (SMD=-0.20, 95%CI -0.31 to -0.08, P<0.001) [FIGURE:6] subscales. No significant difference was found for the uncertainty subscale (SMD=-0.03, 95%CI -0.14 to 0.08, P=0.62) [FIGURE:7].

Decision Regret and Satisfaction Three studies [11,19-20] assessed decision regret using the Decision Regret Scale (DRS) [28]. Due to substantial heterogeneity (I^2=99%, P<0.001), we used a random-effects model, finding no significant difference between groups (SMD=-0.83, 95%CI -7.89 to 6.24, P=0.82) [FIGURE:8]. Three studies [18,20,26] reported that PDAs improved decision satisfaction.

Knowledge All 16 studies reported PDAs' effect on patient knowledge. Ten studies [11,13-14,17-20,22-24] were included in the meta-analysis. Due to high heterogeneity (I^2=95%, P<0.001), we used a random-effects model, which showed PDAs significantly improved knowledge levels (SMD=0.88, 95%CI 0.52-1.24, P<0.001) [FIGURE:9]. Studies not included in the meta-analysis [12,15-16,21,25-26] also demonstrated that PDAs effectively improved knowledge and accuracy in answering disease-related questions, helping patients understand clinical issues regarding disease treatment and risks.

Publication Bias and Sensitivity Analysis

Funnel plot analysis for decisional conflict showed asymmetry, suggesting potential publication bias [FIGURE:10]. Sensitivity analysis was performed by

sequentially removing each study to assess its impact on the outcome. All results remained robust, indicating stable findings.

Discussion

Enhancing PDAs Development Quality Based on IPDAS 4.0

IPDAS 4.0 comprises 44 items across three categories—qualification, certification, and quality standards—providing fundamental specifications and scientific guidance for PDA development and application. In the qualification domain, all 16 included tools met the six criteria, listing health problems, decision questions, alternative options, benefits, risks, and patient experiences. In the certification domain, items B7-B10 are specific to test PDAs; only two test PDAs [18,22] were included, and neither reported: (1) next decision steps based on test presence/absence, or (2) lead-time bias (informing patients that screening can detect health/disease states without clarifying that results may not improve outcomes beyond standard care). The remaining 14 tools [11-17,19-21,23-26] only addressed B1-B6: balanced presentation of pros/cons, evidence citations, development dates, update strategies, probability formats, and funding disclosures, but did not address PDA update strategies.

In the quality domain, items C24-C28 address true positives, true negatives, false positives, false negatives, and diagnostic accuracy for test PDAs; neither of the two test PDAs [18,22] addressed these. Items C1-C23 require PDAs to present probabilities using data, charts, and text; consider patient values and preferences; use question prompts to guide clinician-patient communication; include development processes with participating and non-participating patients and clinicians; specify evidence selection and integration methods; report evidence quality; include developer qualifications; and specify readability levels. The 16 included PDAs met 14-23 criteria each, but failed to address: using question prompts to guide communication, including participating/non-participating patients and clinicians in development, specifying evidence selection/integration methods, reporting evidence quality, specifying readability levels, and providing evidence for "concordance between informed patient preferences and their choices."

PDAs should be developed based on patient-centered design principles as a crucial pathway to promote SDM. We recommend that Chinese scholars strictly adhere to IPDAS quality control standards during development, application, and reporting. However, since IPDAS 4.0 lacks explicit scoring guidance and uses subjective 1-4 ratings, researcher bias may affect objectivity. Further exploration is needed on how to scientifically apply IPDAS 4.0 for quality evaluation.

Improving PDAs Application Quality Based on Four Characteristics of Informed Decision-Making

Decisional conflict and regret are important outcome measures for decision quality, related to decision complexity [29]. When health decision outcomes differ

substantially from expectations, patients may experience decisional conflict, delayed decisions, or decision regret, affecting physical and psychological health, quality of life, and potentially causing medical disputes [28,30-31]. Decisional conflict refers to patients' internal uncertainty about treatment choices, comprising five dimensions: informed, values clarity, support, effective decision, and uncertainty [28].

From a cognitive psychology perspective, informed decision-making involves two components: "informed" and "decision." "Informed" means being made aware of information about problems and specific options' advantages/disadvantages, forming the basis for attitudes and behaviors. "Decision" follows, representing attitude formation—a complex psychological process including compliance, identification, and internalization. Compliance is superficial change; identification involves adapting to external environments; internalization represents deep, stable attitude change from genuine belief.

Therefore, PDAs-based informed decision-making should reflect four characteristics [8]: (1) **Intersectionality**—meeting specific population cultural needs; (2) **Inclusive design**—accessible and applicable to most individuals; (3) **Organizational health literacy**—healthcare institutions equitably helping patients understand and implement health decisions; and (4) **Health numeracy**—providing scientific data to help patients choose personalized treatments based on needs and preferences.

Given varying patient education levels and PDA acceptance, personalized PDAs should be provided for different health literacy levels. PDA formats include paper booklets, audio tapes, videos, and web programs. Paper booklets are concise, understandable, low-cost, and clearly present treatment options, making them suitable for elderly patients. Web-based PDAs integrate text, images, and animation with interactive, personalized features, offering freedom, convenience, and strong dissemination, suitable for patients with adequate health literacy (e.g., WANG et al.' s [11] digital SDM toolkit with patient feedback and knowledge assessment). Clinicians should fully consider patients' physiological characteristics, psychological needs, and cognitive levels to develop different PDA types based on individual differences, helping patients choose treatments aligned with their values, preferences, and needs.

Study Limitations

This study has several limitations: (1) Some studies did not provide PDA examples, potentially introducing bias during IPDAS 4.0 evaluation; (2) Heterogeneity existed across included studies due to differences in population geography, sociocultural background, education/economic levels, and assessment tools; (3) Due to the nature of PDA interventions, blinding of interventionists and participants was difficult—only two studies [14,20] explicitly reported blinding, though this had minimal impact on objective outcome measures. Sensitivity analyses confirmed stable meta-analysis results, suggesting our findings are reliable.

Conclusion

PDAs increase CVD patients' knowledge and reduce decisional conflict, thereby improving satisfaction. Their effect on reducing decision regret requires further investigation. Clinicians should consider patients' health literacy, economic capacity, and disease severity to develop personalized PDAs [32]. Chinese scholars should strictly follow IPDAS quality control standards in development, application, and reporting. Further research should explore how to scientifically apply IPDAS 4.0 for quality evaluation. Future large-sample, multicenter, high-quality studies are needed to more objectively and comprehensively evaluate PDAs' effects on decision quality in CVD patients and provide more evidence for PDA development.

Author Contributions: PEI Zhiyi: study conception/design, implementation, manuscript writing; ZHANG Xiaoxin, LIN Jiayi: data collection and analysis; ZHANG Xiangyi: feasibility analysis and manuscript revision; KANG Xiaofeng: quality control, overall responsibility, and supervision.

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Conflict of Interest Disclosure: The authors declare no conflicts of interest.

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