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Review

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Decision aid program affect regret in patients with prostate cancer treatment: a systematic review of randomized controlled trials

[Short title: **Decision aid can affect the regrets level of prostate cancer patients**]

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Abstract

Introduction: Long-term treatment and associated side effects can affect a patient's quality of life, one of which is the patient's regret during the treatment program of prostate cancer. The Decision Aid (DA) program can help patients with chronic diseases to face disease treatment, but the effect on the treatment of prostate cancer patients has not been evaluated further. This

study aims to assess the effect of a decision aid program on treatment regret in prostate cancer patients.

Methods: This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA) guidelines with the search engines PubMed and Google Scholar from January–March 2023. The inclusion criteria used were randomized controlled-trial studies with full text in English, published for the last ten years, the decision regret during or after treatment program was reported and the type of regret measurement was described.

Results: Based on a literature search, 5 studies met the inclusion criteria. The relationship between decision aid and regret was not significantly lower, but has significant effect for long-term (12 months) and in minority ethnic. Studies on a wider and heterogeneous population are needed to assess the effect of decision aids on the perspective of patients with prostate cancer programs.

Conclusions: Decision aid may affect the level of regret of prostate cancer patients in the treatment program.

Key words: clinical trial, meta-analysis, prostate cancer

Introduction

According to global data in 2018, prostate cancer accounted for 7.1% of all cancer cases in men, making it the most frequent cancer among men and increasing in elderly [1]. Prostate cancer is also the second most important cause of mortality after lung cancer [1]. There are several risk factors for prostate cancer, including age, family history, race/ethnicity, and lifestyle factors such as diet and physical inactivity [1–3]. Prostate cancer also causes a lot of burden costs. A study found that the direct medical costs of prostate cancer care in the United States in 2010 were estimated to be \$12.1 billion, and the indirect costs were estimated to be \$6.2 billion, while in China the total economic burden of prostate cancer was ¥15.48 billion (\$2.41 billion), with the largest portion of costs attributed to hospitalization and surgery [1].

Management options for prostate cancer depend on the cancer stage, presence of high-risk features, and the patient's life expectancy [4]. The therapeutic strategies available today

consist of loco-regional treatments (radical prostatectomy, radiation therapy) and general treatments (chemotherapy and androgen deprivation therapy) [4]. Side effects that may arise from the therapy performed surgery and androgen deprivation therapy, can affect urinary, bowel, sexual, and hormonal functioning [4, 5]. Side effects from the treatment given may impact adherence to treatment. This condition will have a negative impact on the patient's quality of life. Therefore, the impact of potential adverse effects of treatment on quality of life should be discussed with the patient prior to treatment initiation [6]. One of the effects of prostate cancer treatment that affects patients is the patient's regret for the choice of treatment, considering the age of elderly patients in most prostate cancer patients can worsen the quality of life [7].

Patient decision aids (DA) are tools designed to support patients in making informed decisions about their healthcare based on scientific evidence [8]. Based on the International Patient Decision Aid Standards (IPDAS) checklist, to be used by patients in clinical settings, DA must be developed by qualified developers, peer-reviewed by colleagues who did not participate in the development or patients, and have been field tested for clinical settings to gain acceptance, balanced with patients who refuse aid and can be used by patients who cannot read [9]. Its use in clinical settings, especially in primary health care, can provide disease information for patients, increase patient risk knowledge, avoid conflicting decisions, and reduce decision conflict from feeling not informed about their management [10].

These tools are meant to be used as a part of a shared decision-making process, where healthcare professionals and patients work together to discuss treatment options and empowering patients to become more involved in the decision-making process [11]. Several studies have shown that DA tools can reduce regret in patients undergoing cancer treatment, one of which is patients undergoing prostate cancer treatment [12]. However, these findings need to be evaluated in a wider and more diverse population for the application of DA in clinical practice. This review aimed to discuss the effect of DA on the treatment regrets of prostate cancer patients.

Methods

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA) guidelines [13].

Search strategy

Literature searches were conducted with the search engines PubMed and Google Scholar from January–March 2023 with a search limit for studies published less than 10 years. The keywords used were “decision aid”, “prostate cancer treatment”, “treatment regret”, and “decision regret”.

Eligibility criteria

The inclusion criteria used were randomized controlled-trial studies with published full-text in English, study focused on patient with prostate cancer, the decision regret during or after treatment program was reported, and the type of regret measurement was described. The exclusion criteria used were a review, systematic review, or meta-analysis, the study was not conducted in prostate cancer patient, study not conducted decision aid for treatment program, and decision regret measurement was not reported.

Data extraction

One investigator (MLA) assessed and extracted from included article namely: study (type of study, year of publication, location), patients (number, mean of age, and sex), intervention (length of study, type of intervention and control, and dosage), and statistical result of outcome. After all data extracted, two investigators (MLA, WNU) assessed the risk of bias of the study using Version 2 of the Cochrane risk-of-bias tool for randomized trials (RoB-2). When there were differing results, a third author (MDP) would assess the risk of bias in the studies.

Results

Selection of study

From the literature search, we identified a total of 989 studies. After screening titles and abstracts, we then reviewed the 12 selected articles for further review. Furthermore, we found six studies that did not report or assess regret scores and one cross-sectional study. After a thorough review, we identified five studies that met the inclusion criteria [14–18] (Figure 1).

Study characteristics

Studies that match the identification of our inclusion criteria were published between 2012–2021 two studies were conducted in North America (Canada and USA) and 3 studies in Western Europe (Netherlands and Scotland). All control groups received usual care by

meeting with a urologist or with the prostate cancer education website. A total of 1295 prostate cancer patients with 517 patients in the control group and 778 patients in the intervention group. Patients in the study were newly diagnosed patients with low-intermediate T1–T3 risk. Four studies used DA with a personal approach via face-to-face, online, or telephone, and one DA used an application approach. The results of the characteristic extraction studies are included in Table 1.

DA content

In four studies, DAs content provided information about prostate cancer, treatment options, side effects of therapy, and education. In one study, DAs prostate cancer patients were given an application to reflect on factors that could influence decisions.

Regret assessment

A total of 3 studies using the Decisional regret scale by Brehaut et al with one study using the Decisional regret scale by Brehaut et al. to construct a new regret scale, and one study using the decision regret scale by Connor AM. Based on data extraction, the use of DAs did not significantly affect regret between 3 to 6 months and one study showed no effect of using DAs on regret for prostate cancer treatment. The effect of DAs on regret was found to be significant at 12-month follow-up, and had an effect on certain groups. Results from the extraction of regret ratings from the included studies in Table 2.

Risk of bias assessment

The results of the risk of bias assessment based on RoB-2 are shown in Figures 2A, B. Two studies showed low bias with three other studies with 'some concerns' bias. In three studies, bias occurred in the D2 domain because the intervention required the researcher's knowledge of the intervention.

Discussion

Based on our findings, the use of DAs in a prostate cancer treatment program on patient regret has a long-term effect on treatment with a more significant effect in minority population groups. Deciding on the best treatment or screening option can be difficult. People may use decision aids when there is more than one choice and neither is better or when the options have benefits and drawbacks that people value differently [19]. Treatment regret influences the patient's perspective on cancer management programs because it takes a long

time and affect quality of life [20]. Although the use of DA has been widely used in clinical settings, its effect on the patient's perspective has not been extensively studied.

DAs have long been used to enhance shared-decision making (SDM) to provide information related to cancer treatment [21]. HR is a process of making collaborative decisions between patients and their physicians through cooperative and intensive communication [22, 23]. More active involvement during treatment decision-making can lead to decreased decision conflicts and lower regrets [24]. However, in several clinical studies, physicians and specialists such as oncologists and radiology often do not provide a role for patients to be more active in SDM as a result [25–27]. Although in different settings DAs can increase the empathy of physicians [28, 29], not yet many guidelines address this implementation in prostate cancer patients [30]. Further research is needed to determine the effect of DAs on empathy which can support patient HR and affect treatment regret.

The use of decision aids has been widely used to assist in the selection of treatment. In use in chronic diseases, such as diabetes, the use of the DAs program helps patients in treatment management and therapy targets so that patients become more aware of the risk of myocardial infarction as a complication and improve treatment adherence [31]. Also, another study in case of depression treatment shows the use of DAs can increase knowledge and improve decision conflicts during treatment [32]. A Cochrane systematic review also stated that patients with exposure to DAs can be more influential, reduce decision conflict, and gain a better risk perspective [33]. Decision aids also increase the patient's role in decision-making between the physician and the patient by opening the patient's thoughts, asking questions about their treatment options, and providing an active role for the patient [34].

In healthcare settings, both cancer- and non-cancer-related, lower involvement in the decision-making process is associated with increased decision regret [27]. Increased levels of decision regret are associated with significant health impacts including lower health-related quality of life, poor self-image, negative judgments of masculinity, increased cancer-related distress, poorer overall health outcomes, and subsequent negative experiences with the health system [35]. Other factors that can exacerbate decision regret for a patient diagnosed with prostate cancer include anxiety before treatment; post-treatment side effects (e.g.: decreased sexual function, bladder, and intestines); higher levels of decision conflict before selecting treatment, and lower satisfaction with the information provided by doctors [35, 36]. Also, decisional regret is more experienced in minorities ethnic caused by treatment that affects quality life and social determinants of health [37]. Based on this study, DAs can help improve

decisional regret in prostate cancer treatment, especially one of our studies showing its effect on minority group decisional regret.

Our findings suggest that a significant effect on a minority group such as African Americans may be influenced by a more significant risk of decisional regret in that group [38]. A systematic review by DeRosa et al. [37] showed that decision-making interventions were associated with positive outcomes such as better literacy, improved patient engagement, less decision regret, higher satisfaction, and more positive communication. This study shows that DAs interventions have positive results in minority groups, so that interventions that focus on these groups are needed to provide good treatment outcomes and minimize side effects that can impact quality of life.

Although our review suggests DA is useful in prostate cancer patients, there are limitations to this study. Firstly, the number of studies we cover is small. This limitation is due to our selection of publications that focus on English language publications, thereby excluding similar studies published other than English. The studies we included were also limited to certain countries (North America and Europe), which may be due to the implementation of their use that has not been widely used in other countries, especially in countries with limited clinical resources. In addition, several studies have used DAs measurements that have not been standardized and used different regret decision scale ratings in several studies so that the conclusions on changing the regret scale are different. Further studies in larger and heterogeneous populations are needed to assess the effectiveness of DAs in influencing patient decision regret.

Conclusions

Decision aids are useful in assisting patients' treatment decisions and affect the decision regret of prostate cancer treatment. Improvements in decision regret were seen over long periods of treatment and in certain groups. Its application in a wider clinical setting is needed to help facilitate the accessibility of prostate cancer patients. Further studies are needed in a wider and heterogeneous population to assess the effect of DAs on patients' quality and function of life.

Article information and declarations

Author contributions

Study concept and design: Muhammad Luthfi Adnan and Widyo Nugroho Utomo; data acquisition: Muhammad Luthfi Adnan; data analysis: Muhammad Luthfi Adnan; drafting of manuscript: Muhammad Luthfi Adnan and Widyo Nugroho Utomo; critical revision of the manuscript: Miranti Dewi Pramaningtyas.

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Conflict of interest

There is no conflict of interest.

Supplementary material

None.

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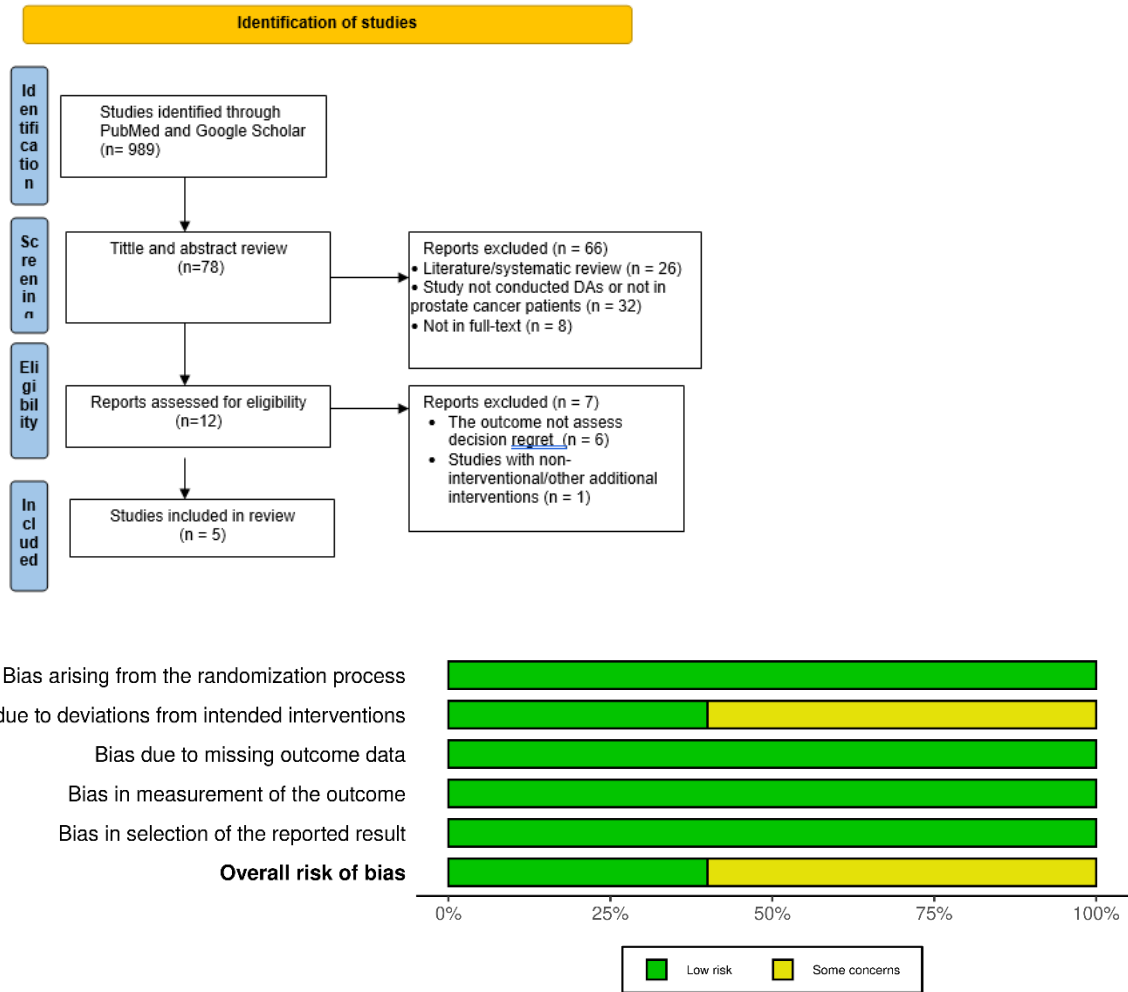


Figure 1. Flowchart of literature search and included study

		Risk of bias domains					
		D1	D2	D3	D4	D5	Overall
Study	Feldman-Stewart et al	+	+	+	+	+	+
	Hacking et al	+	-	+	+	+	-
	Tol-Geerdink et al	+	-	+	+	+	-
	Cuypers et al	+	+	+	+	+	+
	Berry et al	+	-	+	+	+	-

Domains:
D1: Bias arising from the randomization process.
D2: Bias due to deviations from intended intervention.
D3: Bias due to missing outcome data.
D4: Bias in measurement of the outcome.
D5: Bias in selection of the reported result.

Judgement
- Some concerns
+ Low

Figure 2. (A) Domain of risk of bias assessment; **(B)** overall result of risk of bias

Table 1. Summary of included study

Author (year of study)	Country	Participants	Number of participants	Type of DAs	DA content
Feldman-Stewart et al. (2012)	Canada	Newly diagnosed prostate cancer early-stage disease patients with low- or intermediate-risk	81 (intervention group) and 75 (control group)	Values clarification exercises (Val Ex)	Explicit exercises (require that the patient does an action — such as move bars, add weights to a scale, or produce numbers) to reflect the relative impact of particular values on the patient's decision and implicit values clarification providing only information that is related specifically to the decision. Val Ex group received questions relating to the attributes which can affect their decisions
Hacking et al. (2012)	Scotland	Patient with localized or early-stage primary prostate cancer	60 (control) and 63 (intervention)	Personal decision navigator	Identifying and framing key questions regarding cancer management options for patients
Tol-Geerdink et al. (2015)	Netherland	Patients with primary localized prostate cancer (T1-3a)	77 (control) and 163 (intervention)	Decision consultation	Description of each treatment, risk information regarding the outcome (bNED and survival) and side-effects (erectile, urinary, and bowel), the 10-year risk of prostate cancer-specific mortality after radical prostatectomy, and external beam radiotherapy
Cuypers et al. (2019)	Netherland	Patients newly diagnosed localized low or intermediate risk prostate cancer (T1-	111 (control) and 273 (intervention)	Web-based DA	General information about Pca (localized prostate cancer), surveillance, and information detailed about treatments consisted of information about procedures, risks, and pros and cons

		T2N0M0)			
Berry et al. (2021)	USA	Prostate cancer patient with cT1 or cT2 of any risk level from a biopsy-proven diagnosis	194 (control/usual care) and 198 (intervention)	The Personal Patient Profile — Prostate (P3P) decision aid	A web-based intervention that provides patients with personal preferences, values, and concerns relevant to localized prostate cancer (LPC) and provides personalized training and education based on user priorities

Table 2. Data extraction from included study

Author (Year of study)	Duration of follow-up	Type of regret measurement	Result	Key findings
Feldman-Stewart et al. (2012)	3 months after treatment was completed (3-month follow-up) and 12 to 18 months after the decision (> 1-year follow-up)	the Decisional regret scale by Brehaut et al. (Medical Decision Making, 23, 2003, 281)	No significant differences after a 3-month follow-up (Val Ex 7.2 vs. information 7.7), but the mean regret of the Val Ex group was significantly lower (7.2 vs. 8.5) ($t = 2.0$, $p = 0.047$) after a 1-year follow-up. There was no association between marital status and regret between the groups	Interventions that provide benefits to the patient's decision-making process can reduce feelings of regret after undergoing prostate cancer treatment
Hacking et al. (2012)	6 months	Decision regret scale by Conor AM (1996)	There were significant difference between mean score of both groups from 17.1 (16.0) in control and 10.8 (13.7) in intervention ($p = 0.036$)	Interventions that provide physicians with accurate evidence-based information to support decision-making and identify patient preferences that lead to good doctor-patient communication for a better shared decision-making process
Tol-Geerdink et al. (2015)	18 months (6 months and 12 months later)	New regret scale by Tol-Geerdink et al. with the Decisional regret scale by Brehaut et al. (Medical Decision Making, 23, 2003, 281) as comparison	There were no significant difference scale from 15.7 (15.3) in control and 14.2 (14.9) in intervention group during 6 months ($p = 0.52$) and 19.6 (16.6) and 16.1 (16.2) during 12 months later ($p = 0.19$)	There was no increase in regret rates between before and after the study, although intervention in the group with serious morbidity could assist the decision-making process

Cuypers et al. (2019)	18 months (6 months and 12 months later)	the Decisional regret scale by Brehaut et al. (Medical Decision Making, 23, 2003, 281)	The means score between groups were 13.4 (14.5) in control and 17.4 (20.6) in intervention group during 6 months and 12.7 (15.4) and 13.5 (16.9) during 12 months later. There is no statistically lower association between using DA with regret scores (OR 0.61, 95% CI 0.27–1.37)	Intervention using DA did not statistically affect regret in prostate cancer patients
Berry et al. (2021)	6 months	the Decisional regret scale by Brehaut et al. (Medical Decision Making, 23, 2003, 281)	The median and mean DR scores between the P3P and UC groups were 10 (range 0–25) and 15 (range 0–25), 14.38 (SD = 16.32) and 17.07 (SD = 19.04) with no significant difference between the P3P intervention group compared to the control group ($p = 0.36$). Univariate analysis showed that African American, patients with hormonal and bowel symptoms reported a higher estimated DR score ($p = 0.02, 0.009, 0.03$) than the other groups	Although the intervention using decision aids did not statistically affect regret in prostate cancer patients, there were benefits in the African American group, patients with hormonal and bowel symptoms, and in active surveillance patients