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ORIGINAL RESEARCH

Evaluation of a patient decision aid for opportunistic salpingectomy and salpingectomy as sterilization method to prevent ovarian cancer

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Abstract

Introduction: A patient decision aid on opportunistic salpingectomy and salpingectomy as a sterilization method has been developed to provide uniform counseling and reduce practice variation. The aim of this study was to evaluate the use of the patient decision aid in daily clinical practice to ensure its effectiveness and usability, as well as its influence on the decision-making process and the decision of opportunistic salpingectomy.

Material and Methods: As part of the STOPOVCA-implementation study, we conducted a multicenter observational study in 16 hospitals between July 2020 and February 2024. Patients who were eligible for opportunistic salpingectomy were invited to use the decision aid while they considered whether or not to undergo opportunistic salpingectomy. Digital questionnaires were used to evaluate the decision aid, the decision process, and patients' decisions 6–8 weeks post-surgery.

Results: 425 out of 542 patients participated in the questionnaire. A majority of these 425 patients received ($N = 357$; 84%) and used the decision aid ($N = 347$; 82%). Two thirds ($N = 234$; 67%) of those who used the decision aid stated that it increased their knowledge of opportunistic salpingectomy. Patients considered the decision aid a usable aid, allocating a score of 8.1 out of 10 and would recommend it to other patients facing the decision regarding opportunistic salpingectomy. Patients considered the extent to which they were involved in the decision-making process as high, and the

Abbreviations: IPDAS, International Patient Decision Aid Standards; OS, opportunistic salpingectomy; PrepDM, Preparation Decision Making; PtDA, patient decision aid; SDM-Q9, Shared Decision Making Questionnaire 9; SUS, System Usability Scale.

For affiliations refer to page 1198.

decisional conflict low. The majority of patients who used the decision aid opted for opportunistic salpingectomy (*N* = 326; 95%). Main reasons for choosing opportunistic salpingectomy were the risk-reducing effect of ovarian cancer (*N* = 311; 90%) and the lack of functionality of the fallopian tubes after childbearing (*N* = 320; 92%).

Conclusions: The patient decision aid was used by a majority of patients who received it. The decision aid was regarded by patients as user-friendly, and it was recommended to be used in the decision-making process for opportunistic salpingectomy. Patients stated that the decision aid provides reliable information and increases patients' knowledge of opportunistic salpingectomy.

KEYWORDS

female sterilization, ovarian cancer, patient decision aid, prevention, salpingectomy

1 | INTRODUCTION

Ovarian cancer has the highest mortality rate among gynecological malignancies, with poor five-year survival due to ineffective screening and limited treatment options.[1,2] Evidence indicates that high-grade serous ovarian cancer commonly originates from the fallopian tube epithelium rather than from the ovarian mesothelial lining.[3–5] Retrospective studies show that removing the fallopian tubes reduces ovarian cancer risk by 42%–65%.[6] Although prospective evidence is still being collected, these findings have resulted in recommendations for opportunistic salpingectomy (OS), defined as discussing additional bilateral salpingectomy during pelvic surgery in women who have completed childbearing.[7,8] While no significant differences in surgical complications have been observed with OS, concerns remain about potential long-term effects, such as earlier menopause and decision regret.[9] These concerns contribute to variation in clinical practice regarding counseling and performing OS.[10–12]

Because OS involves a decision with no proven superior option in the long term, it depends on patients individual values and preferences. This makes shared decision-making an appropriate approach. Shared decision-making aims to achieve an informed decision by weighing benefits and risks at the individual patient level.[13,14] For this process, active participation from both patients and physicians is required, with patient preferences and values at the forefront.[14] A patient decision aid (PtDA) can support shared decision-making between patients and physicians by improving the patients' knowledge and risk perception. A PtDA can eliminate uncertainties and decisional conflicts by actively considering the patient's preferences, needs, and values.[15]

To improve shared decision-making, we previously developed and alpha tested an online PtDA according to the International Patient Decision Aid Criteria (IPDAS) on the opportunistic removal of the fallopian tubes.[16,17] To the best of their knowledge, no patient decision aids have been specifically designed for this context before. The aim of this study was to evaluate the use of the PtDA in daily clinical practice (beta testing) to ensure its effectiveness and usability, as well as its influence on the decision-making process and the decision of OS.

Key message

A patient decision aid about the opportunistic salpingectomy was clinically used, praised for its user-friendly design, and recommended for use in the decision-making process and effectively enhancing patient perception of their knowledge.

2 | MATERIAL AND METHODS

As part of the STop OVarian CAncer (STOPOVCA) implementation study (NCT04470921), we conducted a multicenter observational prospective study to evaluate the use of the PtDA in daily clinical practice and the influence of the PtDA on the decision-making process among women who were eligible for OS.

The study was described following the Standards for Universal reporting of patient Decision Aid Evaluation (SUNDAE, Table S1) and the Checklist for Reporting Results of Internet E-Surveys (CHERRIES, Table S2).[17,18]

2.1 | Study process

Between July 2020 and August 2023, women eligible for OS were approached by their treating physician to participate in the study. The eligibility criteria included women indicated for benign intra-abdominal gynecological surgery with at least one ovary preserved, having completed childbearing and/or who would no longer be able to conceive after their planned surgery, and who were at population risk for ovarian cancer. Women aged 30 years

or younger and those unable to understand written or spoken Dutch were excluded. The study was conducted across sixteen hospitals in the South and East of the Netherlands, representing different types of hospitals (academic ($N = 2$), teaching ($N = 11$) and non-teaching hospitals ($N = 3$)).

Patients had two appointments as part of the consent process for OS. After deciding on the need for surgery, patients were invited by their physician to use the PtDA. They received a hand-out containing individual login details to access the online PtDA, allowing them to read the information and specify their personal considerations and preferences to opt for OS of not. The decision on whether to undergo OS was then discussed during the second appointment (by phone) with their physician.

Patients who provided written consent and underwent surgery were asked to evaluate the PtDA and the decision process through an online questionnaire, 6–8 weeks post-surgery (Appendix S1). The questionnaire could be completed in approximately 15 min. If the patient did not complete the questionnaire within a week, an automatic reminder was sent. Figure 1 provides the step-by-step plan of the study process from handing out the PtDA to receiving the evaluation questionnaire.

2.2 | Data collection and analysis

Data were collected between July 2020 and February 2024. Patient demographics were collected from electronic medical records and entered into an electronic database using Castor EDC (Electronic Data Capture) by a local researcher within each participating hospital. Post-surgery, an online questionnaire was sent to patients by email using Castor EDC. Subsequently, pseudonymized demographic and questionnaire data were collected by the principal researchers and descriptively analyzed (frequencies, median, means) using IBM SPSS Statistics, version 24.0 (released 2016; IBM Corp, Armonk, NY). System Usability Scale (SUS), decisional conflict, shared decision-making, and Preparation Decision Making (PrepDM) scores were determined according to the user manuals of the validated questionnaires.[19–22] Statistically significant Pearson correlation coefficients between age, SUS, decisional conflict, shared decision-making, and PrepDM were visualized by a network plot using the 'SemiPar' package (version 1.0-4.2) in R (software version 4.1.2).[23–25] Two-sided p-values of <0.05 were considered to be statistically significant.

2.3 | Outcome measures

2.3.1 | PtDA

The use of the PtDA in daily clinical practice was evaluated by a questionnaire based on accessibility, experiences with, and use of the PtDA. Patients were asked if they received the PtDA and whether they used it. If patients indicated the use of the PtDA, comprehensibility, the ability to maintain focus, personal relevance, and reliability of the PtDA were assessed using questions developed by two researchers (MG, RH) based on previous questionnaires used in similar evaluation studies.[26] In addition, the usability of the PtDA was measured using the validated System Usability Scale (SUS). SUS scores range from 0 to 100. A SUS score below 51 is considered as poor, 51–68 acceptable, 68–80.3 good, and 80.3–100 excellent usability.[19] Furthermore, the IPDAS criteria for effectiveness were assessed (Appendix S2).

2.3.2 | Decision process

The patients perceived involvement in the decision-making process was quantified using the validated Shared Decision-Making questionnaire (SDM-Q-9).[20] Patient perceptions of the PtDA's usefulness in helping them reach an informed choice—particularly through shared decision-making with their physician—were assessed with the PrepDM scale.[21] Both Shared Decision Making Questionnaire 9 (SDM-Q9) and PrepDM scores range from 0 to 100, with higher scores indicating a greater level of shared decision-making or preparation.

2.3.3 | Decision

The patients' final decision to undergo OS or not, their decisional conflict, and reasons regarding the decision were evaluated. The final decision was determined based on information obtained from electronic medical records after cross-referencing with patients' responses in the questionnaire. Decisional conflict was measured using the validated decisional conflict scale.[22] Decisional conflict was defined as the uncertainty about which choice to make, often influenced by risks and personal values. Decisional conflict scores range from 0 to 100. Scores below 25 indicate low decisional conflict, scores between 25

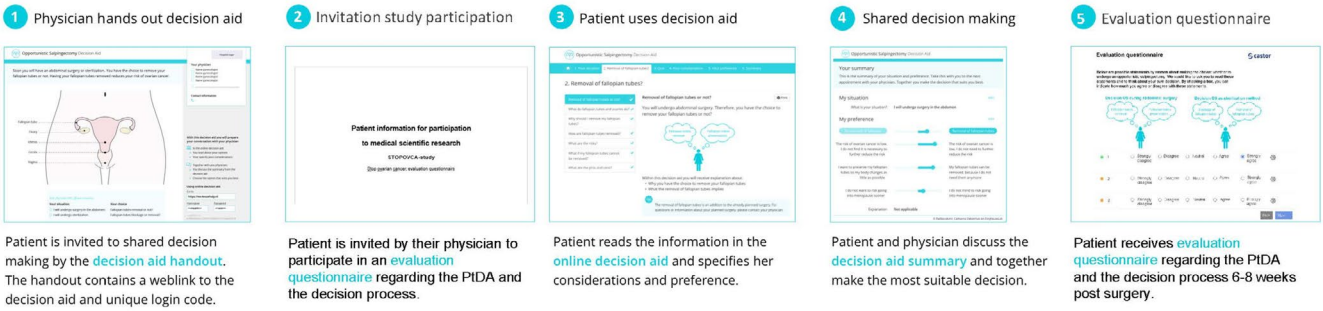

FIGURE 1 Step-by-step plan in the study process from handing out the Patient Decision Aid (PtDA) to receiving the evaluation questionnaire.

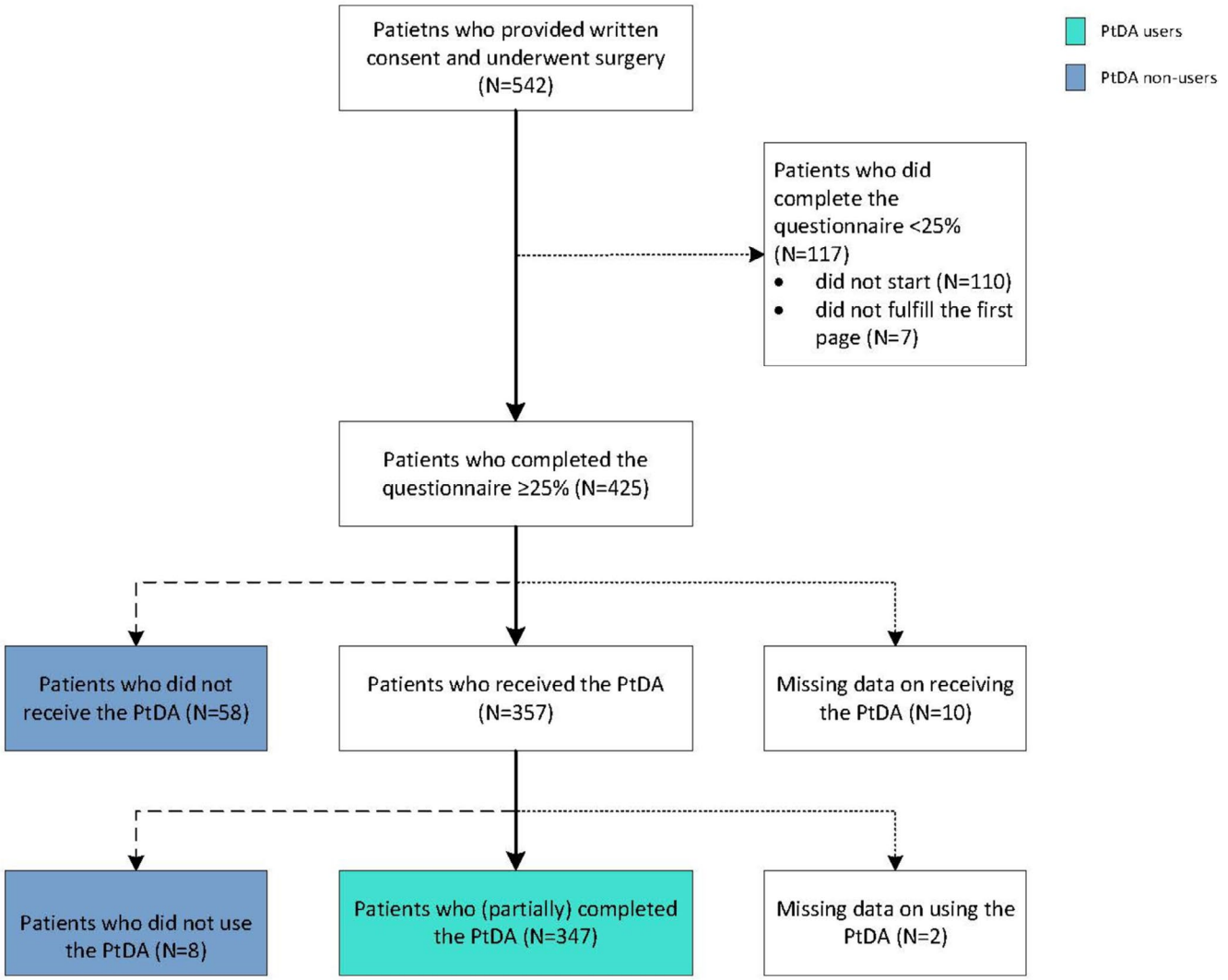

FIGURE 2 Flowchart of the study population. PtDA, Patient Decision Aid.

and 37.5 indicate intermediate conflict, and scores above 37.5 indicate high decisional conflict. Reasons to opt for OS of not were evaluated using predefined statements based on barriers, facilitators, and decisional needs identified by Gelderblom et al.[9] and van Lieshout et al.[16] (Figure 5). These reasons were assessed using a five-point Likert Scale (strongly disagree: 0, disagree: 1, neutral: 2, agree: 3, and strongly agree: 4).

3 | RESULTS

3.1 | Study population

A total of 542 patients gave written consent and underwent surgery. Of the total number of patients surveyed, 78% ($N=425$) completed the questionnaire for more than 25%, and among them, 414 completed it. According to the questionnaire, 84% ($N=357/425$) received the PtDA. The questionnaire was (partially) completed by 347 (97%) patients who used the PtDA. Only eight patients indicated that they had not used the PtDA, and data on using the PtDA was missing for ten participants. A flowchart is presented in Figure 2.

Patients who used the PtDA had a median age of 43 years (range 38–48), and most were treated in a teaching hospital ($N=276$; 80%). The most commonly performed surgery was a hysterectomy ($N=189$; 55%), followed by sterilization($N=99$; 29%). Patient demographics are presented in Table 1. Patient characteristics did not significantly differ between those who participated in the questionnaire and those who did not (most p-values >0.05) (Table S3).

3.2 | PtDA

The majority of the 347 patients who used the PtDA read the PtDA completely ($N=329$; 95%). Regarding comprehensibility and personal relevance, more than 97% of patients indicated a logical flow of information, good readability, and comprehensible text, tables, and illustrations. A small number of patients ($N=13$; 4%) indicated that some information could be omitted as they felt that

TABLE 1 Demographics of PtDA-users ($n = 347$).

Demographics	Total ($n = 347$)
Age, years, median (range)	43 (38–48)
Indicated surgery, *n* (%)[a]	
Hysterectomy	189 (54.5)
Sterilization	99 (28.5)
Cystectomy	21 (6.1)
Salpingo-oophorectomy (unilateral)	34 (9.8)
Diagnostic laparoscopic surgery	1 (0.3)
Other	6 (1.7)
Type of hospital treated in, *n* (%)	
Non-teaching	41 (11.8)
Teaching	276 (79.5)
Academic	30 (8.6)
Country of birth, *n* (%)	
The Netherlands	328 (94.5)
Other	19 (5.5)
Education level, *n* (%)	
None/Primary	3 (0.9)
Pre-vocational school	49 (14.1)
Vocational education	143 (41.2)
Pre-college education/college	116 (33.4)
University	36 (10.4)
Marital status, *n* (%)	
Married/relationship	294 (84.7)
Single/divorced/widowed	53 (15.3)
Decision OS, *n* (%)	
Undergo OS	326 (94.7)
Not undergo OS	21 (5.3)

[a]Percentage of total ($N = 347$) as some patients had an indication for multiple surgeries.

the information given during counseling was repeated in the PtDA. Other patients ($N = 31$; 9%) indicated that they would have liked to receive more detailed information about the indicated surgery, recovery after surgery, and hormonal consequences. Two-thirds of PtDA users ($N = 234$; 67%) perceived that the content of the PtDA increased their knowledge of OS.

Regarding maintaining focus, most patients assessed the length of the PtDA to be just right ($N = 320$; 92%), and a high proportion reported being able to concentrate well while completing the PtDA ($N = 340$; 98%). Patients spent a median of 15 min (IQR 10–20) using the PtDA. As for reliability, patients considered both the information ($N = 341$; 98%) and source of the PtDA reliable ($N = 341$; 98%). The results are presented in Figure 3.

PtDA users recommended the PtDA to other patients facing the decision regarding OS, giving it a mean grade of 8.2 (SD 1.5, $N = 341$) on a scale of 1–10. Furthermore, the PtDA was rated with a mean grade of 8.1 (SD 1.3, $N = 341$) on a scale of 1 to 10. The mean SUS score was 72.2 (SD 12.1, $N = 341$), indicating good usability. The PtDA met the requirements of 52 out of 56 applicable items from the IPDAS criteria. Appendix S2 explains the IPDAS assessment.

3.3 | Decision process

The perceived level of shared decision-making during the decision-making process was high (SDM-Q9; median 80.0; IQR 64.4–91.1). Decision preparation was assessed as moderate (PrepDM; median 52.5; IQR 30.0–72.5). Detailed information on the SDM-Q9 and PrepDM scores is provided in Figure S1. Figure 4 shows that the usability of the PtDA and being prepared for the decision were associated with a higher perception of shared decision-making and with less decisional conflict.

3.4 | Decision

The majority of the 326 patients chose OS ($N = 326$ 95%; Table 1). Their main considerations for choosing OS were that the fallopian tubes do not have any known function after childbearing ($N = 320$; 92%) and that the risk of ovarian cancer was reduced by OS ($N = 311$; 90%). More than half of the patients ($N = 204$; 59%) indicated that they did not mind the risk of entering menopause slightly earlier. Twenty-one patients (5%; Table 1) chose not to undergo OS. Main considerations for deciding not to undergo OS were the possibility of an earlier menopause ($N = 8$) and to have minimal body changes ($N = 4$). Figure 5 presents all consideration statements for the decision of whether to undergo OS or not.

The majority of patients using the PtDA had low decisional conflict scores (median 17.1; IQR 3.1–25.0). One-fifth of the PtDA users assessed the decisional conflict as intermediate ($N = 51$, 15%) or high ($N = 13$, 4%).

3.5 | PtDA non-users

In total, 66 respondents did not use the PtDA. According to the questionnaire, 58 patients did not receive the PtDA, and 8 patients chose not to use it (Figure 2). These patients had a median age of 44 (IQR 38.5–48.3) and often had a hysterectomy as performed surgery ($N = 42$; 64%). Almost all non-users chose to undergo OS ($N = 65$; 98%). Shared decision-making was mostly assessed as high (median 78.9; IQR 59.4–88.9) and decisional conflict as low (median 21.9; IQR 2.7–26.6).

4 | DISCUSSION

We evaluated the use of the PtDA about OS in daily clinical practice, and the influence of the PtDA on the decision process and decision among women who had completed childbearing and undergone gynecological surgery. Patients considered the PtDA a usable aid and

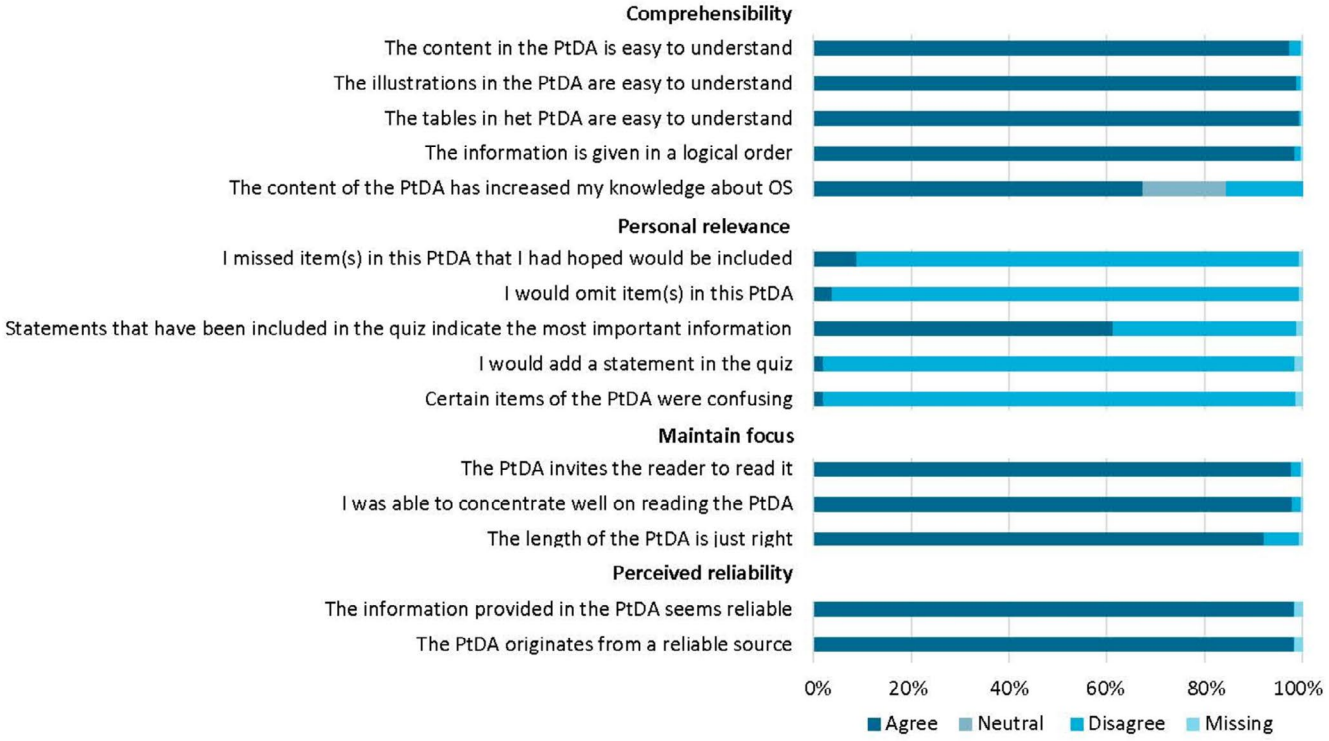

FIGURE 3 Patient responses in the questionnaire on the comprehensibility, personal relevance, maintaining focus, and reliability of the Patient Decision Aid (PtDA). The percentage is calculated as total responses per question of patients who used the PtDA ($N = 347$). OS, opportunistic salpingectomy.

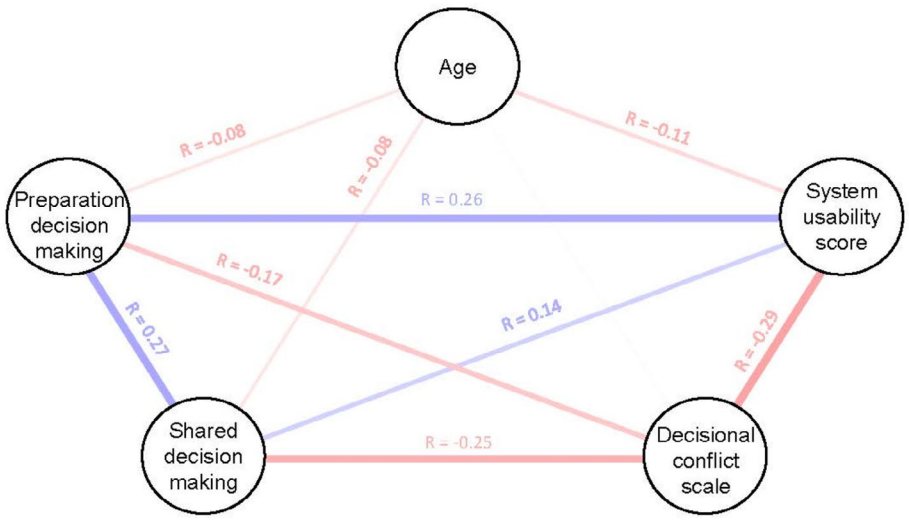

FIGURE 4 Statistically significant ($p < 0.05$) correlations between age, System Usability Scale (SUS), Decisional Conflict Scale (DCS), shared decision making (SDM), and preparation decision making (prepDM). Blue lines illustrate positive correlations; red lines illustrate negative correlations, based on Pearson correlation coefficients.

stated to recommend it for use in the decision regarding OS. Patients experienced the extent to which they were involved in the decision-making process as high and the decisional conflict as low.

The majority of patients who received the PtDA used it. Overall, PtDA users considered its comprehensibility, personal relevance, ability to maintain focus, and reliability as good. A few patients expressed a preference for more information about the indicated surgery, recovery, and hormonal consequences. However, this information was deliberately omitted from the PtDA, as OS can be performed during a range of different surgeries, each requiring specific counseling.[16] The physician is responsible for providing detailed information about the indicated surgery as part of the regular patient information and informed consent procedure during consultation. Regarding hormonal consequences, the PtDA mentioned the

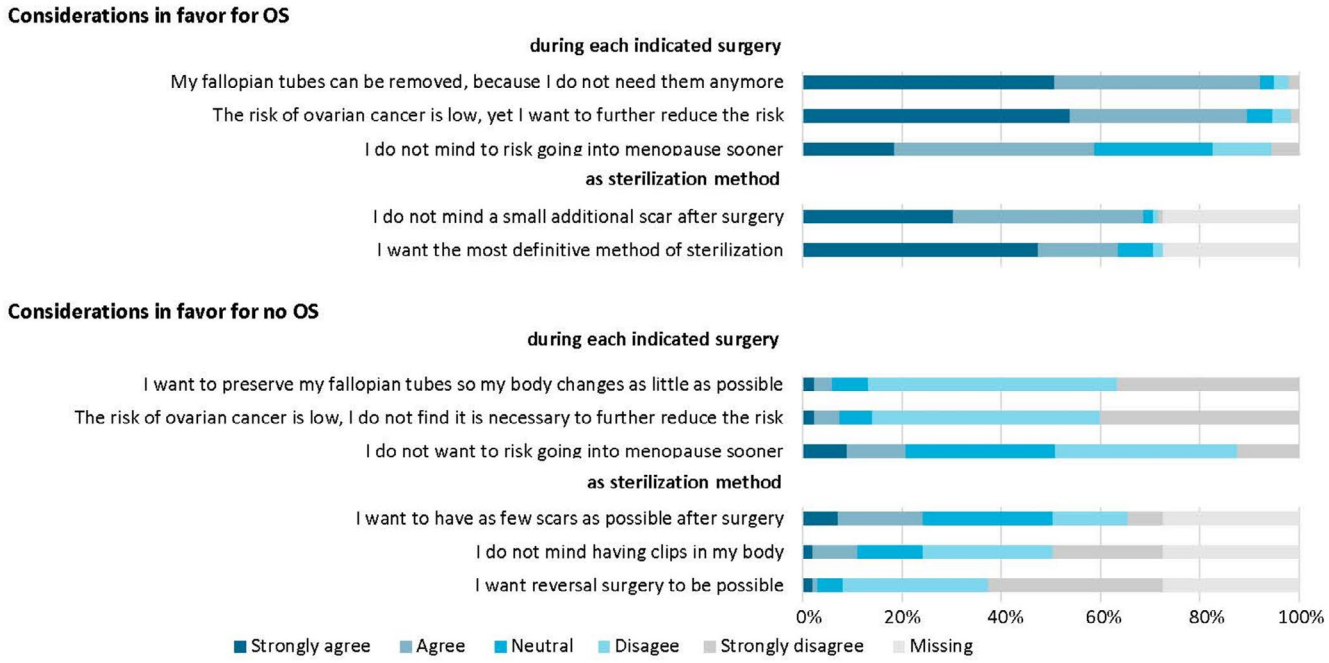

FIGURE 5 Patients' considerations concerning the decision of whether to undergo opportunistic salpingectomy (OS). The considerations are presented for the total group of Patient Decision Aid (PtDA) users receiving any type of surgery ($N = 347$) and for the subgroup of patients undergoing sterilization ($N = 99$).

possibility of entering menopause slightly earlier, with a maximum of 2 years. This represents the most negative scenario based on current evidence, rounded to whole years and presented independently of age to avoid ambiguity.[27] The expected effect on the age of menopause is also influenced by the type of surgery (such as hysterectomy), and an actual effect on menopause is hampered by the lack of long-term evidence.[28] The PtDA highlights that long-term evidence on menopause is still lacking and states that further research will be conducted.

Our study shows that the majority of the included patients opted to undergo OS. The main reasons for this decision were the risk-reducing effect on ovarian cancer risk and the lack of apparent function of the fallopian tubes after childbearing. This results in a skewness of data as a minority of 5% chose not to undergo OS. Although the sample size is limited, it is noteworthy that nearly all patients who chose not to undergo OS made use of the PtDA. A possible explanation for these findings might be patients' perception of increased knowledge about OS after using the PtDA. Studies have shown that better-informed patients are not only more aware of the benefits, but also the risks associated with a decision, leading to a greater satisfaction with their decision.[15] These findings align with evidence from the last decade, which indicates that PtDAs support shared decision, resulting in better-informed patients and lower decisional conflict.[15]

The PtDA demonstrates effective utilization in daily clinical practice, resulting in low decisional conflict among patients. Moreover, patients reported that the PtDA provides reliable information and increases patients' perception of knowledge on OS. Therefore, it could support the implementation of OS and reduce the current practice variation.[9,12] Further efforts are needed to make this PtDA accessible for the entire patient population, including vulnerable groups. For instance, a read-aloud option could make the information understandable to patients with low literacy and blindness. Translating the PtDA could provide comprehensible information for non-Dutch speakers and contribute to reaching the international public and healthcare professionals. In the case of digital illiteracy, the PtDA should be available to be printed on paper or read together with a medical professional.

According to our findings, 14% of the patients did not receive the PtDA. However, this percentage may even be higher. Previous research has shown that a large proportion of eligible women were not counseled for OS. Therefore, it is likely that some women who were eligible for OS were not represented in this study. To determine whether the PtDA facilitates the implementation of OS, insight is needed into how many patients were actually eligible for OS, how many of them received the PtDA, and how many of them eventually used it. From an organizational point of view, possible explanations include that the PtDA was not yet embedded in the physicians' clinic workflow or was not adequately available at the time of consultation. In addition, previous research showed that barriers for implementation of OS were limited time to provide counseling and the requirement of an additional contact to discuss the findings resulting from use of the PtDA.[9] Although the PtDA could reduce the counseling time of OS during consultation, using the PtDA requires an additional encounter to discuss OS and confirm the final decision. Given the physicians' observation of high acceptance of OS among patients,[9] it is conceivable that some physicians were reluctant to hand out the PtDA. Furthermore,

clinicians themselves may be reluctant to offer OS in certain situations, such as during vaginal surgeries.[9] From the patients' perspective, patients might have sought out alternative sources of information or showed no inclination to use the PtDA.[29] For example, some patients may decide during the primary consultation and therefore decline the PtDA as it is regarded as superfluous. Gaining insight into the workflow is essential to optimize implementation of the PtDA from both patients' and physicians' perspectives. These insights can be used to develop a framework that serves as a guiding principle for integrating OS into daily clinical practice. Ultimately, along with the PtDA, this framework could be widely distributed and made easily accessible for patients eligible for OS. Furthermore, regularly updating the PtDA to incorporate the latest evidence is essential. The use of the PtDA has, namely, the potential to improve equality among patients by providing consistent information and reducing the influence of individual physician perceptions.

Over half of the patients expressed their willingness to accept the risk of going into menopause slightly earlier. However, it is important to note that entering menopause earlier may have adverse health consequences, including increased cardiovascular risk and bone demineralization. Although recent meta-analyses show no significant differences in ovarian reserve between women who have undergone bilateral salpingectomy compared to those who have not undergone bilateral salpingectomy, the long-term effect of OS on menopausal age is unknown.[27,28] Studies like the SALSTER (NCT0386080) and STOPOVCAyoung[30] (NCT04757922) will provide more clarity on this in the future. Until then, patients should be informed about this potential risk.

Recent literature demonstrates the growing interest of OS in surgeries beyond the gynecological scope.[31] OS during cholecystectomy has proven to be feasible.[8,32,33] However, the types of surgery and patients qualifying for OS should be established. Adequate counseling may prove to be a challenge for non-gynecological surgeries since reproductive and endocrine issues fall outside the scope of informed consent processes in general surgery. Currently, only gynecologists counsel and perform OS and female sterilization within gynecological patients. Insight is needed into barriers and facilitators of OS during non-gynecological abdominal surgeries. The developed PtDA could support the counseling process for non-gynecological abdominal surgeries or salpingectomy for sterilization at Cesarean section. However, it would require evaluation and possible adaptation for use within these specific populations.

The strengths of this study were the study size, the high participation and completion rate of the questionnaire, the number of participating hospitals representing academic, teaching, and non-teaching hospitals, and the high number of PtDA users. We used a prospective cohort of patients who were offered the PtDA and OS, aiming to promote uniform counseling and reduce current practice variation. Within this design, patients had the choice of whether or not to undergo OS, enabling shared decision-making and allowing patients to maintain autonomy.[34] However, this study design is accompanied by the skewness of data because the majority of the study population opted for OS. Although the high acceptance rate of OS seems comparable with earlier studies, further investigation into potential biases or influencing factors, such as oncological medical history, seems important. However, based on the current evidence and population characteristics, such as low population risk of ovarian cancer, benign indication of surgery, and relatively young age, the impact of these factors on the decision-making process appears limited.

Moreover, potential selection bias has been introduced by this study design as patients who have not used the PtDA are only represented by a very small group. Data are missing from patients who did not want to participate in the study but received the PtDA and patients who did not complete the questionnaire, although they provided consent ($n = 117$) despite having sent several reminders. One of the reasons for not completing the questionnaire may be the time gap between using the PtDA and receiving the questionnaire. In this study, questionnaires were sent after the surgery to allow patients to reflect on the whole decision-making process. However, delays in surgery, particularly due to factors like COVID-19, may have contributed to a longer time gap with reduced patient engagement and motivation for study participation. Therefore, results should be interpreted with caution. A randomized controlled trial should ideally have been used for a thorough comparison between PtDA users and non-users, where the questionnaire could have been administered immediately after using the PtDA and decision-making.

While we have collected extensive data using validated questionnaires, it is important to note that these data are primarily based on patient self-assessment and should be interpreted with caution. Patient understanding and decision-making are often influenced by subjective perceptions, rather than objective measures. Consequently, patient assessment may lead to overestimation or underestimation of actual comprehension, potentially impacting the reliability of the data.

5 | CONCLUSION

The patient decision aid was used by a majority of patients who received it. The PtDA was regarded by patients as user-friendly, and it was recommended to be used in the decision-making process for OS. PtDA users experienced a high level of shared decision-making, low decisional conflict, and opted mainly for OS. Patients stated that the PtDA provides reliable information and increases patients' knowledge of OS.

AUTHOR CONTRIBUTIONS

All authors contributed to the manuscript. M.E. Gelderblom, C. Fisch, L.A.M. van Lieshout, J.M.J. Piek, J.A. de Hullu, and R.P.M.G. Hermens contributed to the design of the study. M.E. Gelderblom and J. intHout performed the data analysis. M.E. Gelderblom drafted and edited the manuscript. All authors contributed to the data

collection, evaluation of the patient decision aid, and content of the article and have read and approved the final version of the manuscript being submitted for peer review.

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Our PtDA is now freely available in multiple languages. See Supporting Information Figure S1.

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CONFLICT OF INTEREST STATEMENT

The author(s) report no conflict of interest.

ETHICS STATEMENT

The current study was approved by the Radboud Medical Ethical Committee on December 28, 2018 (METC) (2018-4978) and was exempt from the Medical Research Involving Human Subjects Act (Dutch: WMO).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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