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ORIGINAL ARTICLE

Development of a Patient Decision Aid for Targeted Therapy for Relapsed Ovarian Cancer

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Background: Patients with recurrent ovarian cancer often face difficulty choosing treatment such as chemotherapy or targeted therapy. **Aim:** This study aimed to design this patient decision aid (PDA), which presents therapeutic efficacy and cost to help patients make appropriate and personalized treatment decisions. **Methods:** A PDA was developed according to the International PDA Standards (IPDAS), and α and β tests were conducted on 14 healthcare professionals and 10 public representatives as test participants. **Results:** Using a Likert scale, the public representatives gave positive comments about the advantages and disadvantages of the PDA's fair presentation of treatment choices and promotion of doctor–patient shared decision-making (SDM) (average score, 3.7–4.5 points). Similarly, the healthcare professionals were optimistic that this PDA could help patients more easily understand their choices (average score, 4.3–4.4 points). The average anxiety level before and after PDA use decreased from 7.5–5 points (scale, 1–10). **Conclusion:** According to this newly developed PDA, doctors and the public play a pivotal role: the latest medical literature and treatment options are kept up with, and the most correct and updated information is provided for use by doctors and patients. Therefore, the PDA design's original intention and purpose were fulfilled.

Key words: Ovarian cancer recurrence, target therapy, patient decision aid

INTRODUCTION

Current treatment for patients with recurrent ovarian cancer, in addition to chemotherapy and targeted therapy (bevacizumab and poly[ADP-ribose] polymerase [PARP]) inhibitor, has a better clinical therapeutic effect. Multiple studies have shown that, for ovarian cancer with unknown *BRCA* gene mutations, for relapsed patients, regardless of whether they are susceptible to platinum-containing chemotherapy, the use of chemotherapy plus targeted therapy can indeed increase progression-free survival (PFS)[1-5] and overall survival (OS).[1-5] The proportion of patients whose tumors shrank for a certain period after treatment is the objective response rate (ORR).[1-5] This effect has also been recognized by the Taiwan Food and Drug Administration (TFDA). However, the methods of paying for medical expenses and providing drugs are not the same. Patients often have difficulty making choices because of the large amount of information available. Therefore, through the development and production of a patient decision aid (PDA), patients can choose chemotherapy drugs. Together with relevant information such as the effectiveness and financial costs of the target drugs, a preliminary concept can be formulated to help patients make the choice that suits them.

MATERIALS AND METHODS

Implementation objects

The first priority in the treatment of ovarian cancer is killing and inhibiting cancer cells. Conventional chemical

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and target drug therapies are both effective. Owing to the high recurrence rate of ovarian cancer, the addition of target drug therapy increases disease Progression-free survival (PFS),[1-5] overall survival (OS),1-5and the proportion of patients whose tumors shrank for a certain period after treatment (ORR) 1-5 [Table 1] is helpful to some extent, especially at prolonging PFS, increasing susceptibility to first line platinum containing chemotherapy drugs and increasing the reuse of platinum containing chemotherapy drugs in the event of recurrence. Whether a PDA increases target drug treatment options mainly depends on: (1) financial burden (which is relatively high, and only certain groups meet health insurance benefit standards); (2) degree of physical burden (severity of adverse side effects caused by clinical drug reactions); and (3) treatment expectations.

Therefore, we hope that patients can use a PDA to decide which treatments best suit them after being fully provided with the relevant medical information.

Implementation objects and timing

Patients with recurrent ovarian cancer in outpatient, emergency, or hospital settings may choose (or be suitable for) targeted therapy plus chemotherapy after evaluation by an obstetrician/gynecologist.

PDA aids with the following decision-making options: (1) chemotherapy combined with target drug treatment (bevacizumab, vascular inhibitor); (2) addition of an oral target drug (PARP inhibitor) after chemical drug treatment; and (3) chemical drug treatment. The three treatment methods were approved by the TFDA.

Description of research and development process

To develop decision-aid tools, the team selected the topic based on the International PDA Standards (IPDAS)[6,7] and the Medical Policy Council's four-step needs assessment. They selected "I am a patient with recurrence of ovarian cancer." "Selection of maintenance target drugs" was the theme of the development of the PDA, an SDM aid for doctors and patients [Table 2].

Upon selecting the topic, we used a medical literature search engine to identify literature on PDA and used the spirit and search strategy of evidence based medicine to strictly review PICO (patients: adults due to ovarian tumor recurrence); intervention: use of Cochrane, Embase, PubMed, etc., to identify articles; comparison: conventional chemical drug treatment plus targeted therapy; outcome: overall survival (OS). A total of 28 articles were identified in the search. After the deletion of duplicate articles and other limiting conditions according to year, the experimental method (systematic review, randomized controlled trial) and quality of the six documents [Tables 3 and 4] were documented and converted into a PDA.

After the initial PDA production, doctors were consulted for their clinical suggestions at the departmental meeting, and 14 medical staff participants underwent an α test to revise and improve its usability. This PDA was also tested with 10 public representatives through individual interviews to perform α test and β test[8] [Table 1].

The revision of the PDA and the content of testers' questions and suggestions collected during this process will have important impacts on it. The public is unfamiliar with medical terminology, which causes low understanding and may further affect the emphasis on treatment methods they consider. For example, wording suggestions can be made more colloquial to make it easier for patients to understand them. For example, treatment efficacy can be changed to "quality of life." In this version, important statistical terms in the research literature will be defined (e.g., "mOS: median OS indicates survival

Table 1: Decision-making needs survey objects and methods

Respondents	Patient representative	Clinical user representative	Other interests	Relevant medical literature
Source	Outpatient emergency room patients	Obstetricians and gynecologists (including resident physicians and specialist nurses)	None	(1) J Cancer 2018;9:872-9 (2) Gynecol Oncol 2015;139:10-6 (3) Lancet Oncol 2017;18:779-91 (4) Lancet Oncol 2017;18:1274-84 (5) N Engl J Med 2018;379:2495-505 (6) J Clin Oncol 2014;32:1302-8
None	10	15		
How to proceed	Individual interview	Group interview (consisting of precancer committee)		
Survey questions	1. Do you know what ovarian cancer recurrence is? 2. Do you know what treatments are available for ovarian cancer recurrence? 3. How do drug side effects differ under different treatments? 4. How do survival effects differ for different treatments? 5. How do medical costs differ?	1. What are the complications of chemical versus target drugs? 2. When a patient may need surgery, what factors make it difficult for the patient to decide? 3. What do you think are the advantages and disadvantages of targeted therapy? 4. What factors can help patients overcome barriers to decision-making?		

Table 2: Decision-making topic selection table

Project	Content
Why patients must be involved in SDM (summary)	The first priority of treatment for patients with ovarian cancer is to kill cancer cells and inhibit their growth. Conventional chemotherapy and targeted therapy are both reasonable options. The choice mainly depends on (1) Degree of financial burden (2) Degree of physical burden on oneself; and (3) Treatment expectations Therefore, using a PDA, patients can make the decision that best suits them upon fully understanding the relevant medical information and their needs
Decision-making questions	I am a patient with recurrent ovarian cancer. How can I choose the best maintenance target drugs for me?
Decision type	Treatment (including prevention)
Applicable objects (target group)	Adults (>20 years old) with clear consciousness and stable vital signs, those with ovarian cancer who are hospitalized for treatment, or those who seek outpatient treatment due to suspected recurrence
Decision options	(1) Conventional chemical drug treatment; (2) Conventional chemical drugs + target drug treatment; and (3) Conservative drug treatment
SDM starter	Attending physician, department of obstetrics and gynecology
SDM facilitator (coach)	Resident physicians in the obstetrics and gynecology department, rotational training residents in various departments (general medicine, emergency department, and family medicine), and specialist nurses
Implementation place and timing	Outpatient, ward (when inpatient), and emergency consultation
PDA form	Complete PDA paper form, Zuvio questionnaire (mobile app), Google form (computer) Using the app rather than traditional paper forms makes it easier to share this information with family members and care team colleagues participating in decision-making
PDA provides pipelines and usage methods[3]	Physical (paper), patient's own online download (QR code, website link provided), etc., If you need to think about it before deciding at the next diagnosis and treatment session or discuss it with your doctor, relatives, or friends, you can also record the results of such discussions on your PDA
Implementation strategy	(1) When other medical personnel come into contact with patients with suspected recurrence of ovarian cancer, they should consult with obstetricians and gynecologists to evaluate whether to initiate SDM (2) After approval by the hospital, relevant posters will be produced and placed in conspicuous places in the hospital for reference by patients and their families

PDA=Patient decision aid; SDM=Shared decision-making; QR=Quick-response

time after recurrence"), while relevant graphical symbols will be used to help the public link the considered factors to the table (e.g., economic factors and the required fees are marked with a copper plate [] symbol) to help patients more quickly

Table 3: Empirical evidence-based medicine data

Item	Title	Source
1	Shimokawa M, Kogawa T, Shimada T, Saito T, Kumagai H, Ohki M, *et al*. Overall survival and post-progression survival are potent endpoint in phase III trials of second/third-line chemotherapy for advanced or recurrent epithelial ovarian cancer	J Cancer 2018;9:872-9
2	Aghajanian C, Goff B, Nycum LR, Wang YV, Husain A, Blank SV. Final overall survival and safety analysis of OCEANS, a phase 3 trial of chemotherapy with or without bevacizumab in patients with platinum-sensitive recurrent ovarian cancer	Gynecol Oncol 2015;139:10-6
3	Coleman RL, Brady MF, Herzog TJ, Sabbatini P, Armstrong DK, Walker JL, *et al*. Bevacizumab and paclitaxel-carboplatin chemotherapy and secondary cytoreduction in recurrent, platinum-sensitive ovarian cancer (NRG Oncology/Gynecologic Oncology Group study GOG-0213): A multicentre, open-label, randomized, phase 3 trial	Lancet Oncol 2017;18:779-91
4	Pujade-Lauraine E, Ledermann JA, Selle F, Gebski V, Penson RT, Oza AM, *et al*. Olaparib tablets as maintenance therapy in patients with platinum-sensitive, relapsed ovarian cancer and a BRCA1/2 mutation (SOLO2/ENGOT-Ov21): A double-blind, randomized, placebo-controlled, phase 3 trial	Lancet Oncol 2017;18:1274-84
5	Moore K, Moore K, Colombo N, Scambia G, Kim BG, Oaknin A, *et al*. Maintenance olaparib in patients with newly diagnosed advanced ovarian cancer	N Engl J Med 2018;379:2495-505
6	Pujade-Lauraine E, Hilpert F, Weber B, Reuss A, Poveda A, Kristensen G, *et al*. Bevacizumab combined with chemotherapy for platinum-resistant recurrent ovarian cancer: The AURELIA open-label randomized phase III trial	J Clin Oncol 2014;32:1302-8

assess their own priorities. Finally, based on the completed PDA field exercises, they will be filmed for the public to watch to increase their understanding of the PDA's content. Based on the valuable information obtained from the above β test, the PDA was revised and optimized [Table 5] as the final version [Figure 1].

Ethical statement

The IRB approval was exempted from our IRB as

1. Nonnamed, noninteractive, and nonintrusive research conducted in public, and in which no specific individual can be identified from the information collected
2. Use information and research articles that have been legally disclosed to the public, and the use of the information is consistent with the purpose of the disclosure.

Table 4: Evidence file

Result	Study name and size	Event		Effect	Quality of evidence
		Chemo	Chemo+target drug		
Median overall survival	GOG213 674 people Tracked for 49.6 months	214/337 people 37.3 months (95% CI: 32.9–39.7 months)	201/377 people 42.2 months (95% CI: 37.7–46.2 months)	HR=0.829 *P*=0.056	Grade: Moderate CEBM: Level II
	AURELIA 361 people	13.3 months (95% CI: 11.9–16.4 months)	16.6 months (95% CI: 13.7–19 months)	HR=0.85 95% CI=0.66–1.08 *P*<0.174	Grade: Moderate CEBM: Level II
	OCEANS 484 people	32.9 months (95% CI: 8.3–9.7 months)	33.6 months (95% CI: 11.4–12.7 months)	HR=0.95 95% CI=0.351–0.58 *P*=0.65	Grade: Moderate CEBM: Level II
Median progression-free survival	AURELIA 361 people	3.4 months (95% CI: 2.2–3.7 months)	6.7 months (95% CI: 5.7–7.9 months)	HR=0.42 95% CI=0.32–0.53 *P*<0.01	Grade: Moderate CEBM: Level II
	OCEANS 484 people	8.4 months (95% CI: 8.3–9.7 months)	12.4 months (95% CI: 11.4–12.7 months)	HR=0.451 95% CI=0.351–0.58 *P*<0.0001	Grade: Moderate CEBM: Level II
	GOG213 674 people Tracked for 49.6 months	10.4 months (95% CI: 9.7–11 months)	13.8 months (95% CI: 13–14.7 months)	*P*=0.045	Grade: Moderate CEBM: Level II
Objective response rate	AURELIA 361 people	12.6%	30.9%	*P*<0.001 95% CI=9.6%–27%	Grade: Moderate CEBM: Level II
	OCEANS 484 people	57.4% (95% CI: 51.2%–63.7%)	78.5% (95% CI: 73.3%–83.7%)	21.2% 95% CI=13%–29.2% *P*<0.0001	Grade: Moderate CEBM: Level II
	GOG213 509/674 people Tracking imaging	59% (152/260 people)	78% (196/249 people)	*P*<0.0001	Grade: Moderate CEBM: Level II
	Number of studies	Event		Effect	Quality of evidence
		PARP inhibitor	Placebo		
Median tracking imaging	Study 19 265 people	29.8 months	27.8 months	HR=0.73 95% CI=0.55–0.95 *P*=0.021	Grade: Moderate CEBM: Level II
	Study 19 (*BRCA* mutation) 136 people	34.9 months	30.2 months	HR=0.62 95% CI=0.42–0.93 *P*=0.021	Grade: Moderate CEBM: Level II
Median progression-free survival	Study 19 265 people	8.4 months	4.8 months	HR=0.35 95% CI=0.25–0.49 *P*<0.001	Grade: Moderate CEBM: Level II

CEBM=Centre for evidence-based medicine; CI=Confidence interval; HR=Hazard ratio; PARP=Poly (ADP-ribose) polymerase

RESULTS

According to the feedback received during the test, the questionnaire used a Likert scale.[9] Each question was scored from 1 to 5 points, and the questionnaire was divided into an α test version and a β test version for the public and an α test version and a β test version for the medical personnel. In the fourth edition, the public representatives gave positive evaluations of "PDA's fair presentation of the advantages and disadvantages of treatment options" and "the promotion of SDM between doctors and patients" (the average score for each question was 3.7–4.5 points), while the medical staff representatives expressed positive opinions about "PDA's ability to." "Whether it can help patients understand their choices more easily" also holds an optimistic attitude (average score, 4.3–4.4 points).

As for the overall evaluation of the use of PDA to assist doctors and patients with SDM, for the question "What is

Table 5: First draft formation and optimization of how to handle tester questions or suggestions

Project number	Questions or suggested content	Management strategies
1	The title of the table "Patients with ovarian cancer who have relapsed more than 6 months after the last chemotherapy and are susceptible to platinum-based chemotherapy" is a bit too long. It is recommended to change it to "Relapse after more than 6 months" and explain it concisely; the same goes for the second line (change to "recurrence within 6 months")	Accept the modification: The table title is changed to (1) It takes more than 6 months to relapse and is effective platinum-based chemotherapy (2) Relapse within 6 months and is ineffective platinum-based chemotherapy
2	Professional terms such as mPFS, mOS, and ORR are difficult for patients to understand. It is recommended that notes be added at the bottom of the table	Accept modification: Add comments below the table to explain the professional terminology (1) mPFS: Time with better quality of life (2) mOS: Survival time after recurrence (3) ORR: The proportion of patients whose tumors shrink for a certain period of time after treatment. On images, the tumor growth slows down or the tumor becomes smaller
3	There are so many common side effects that it can be confusing to see, and relapsed patients already have a basic understanding of the side effects of chemotherapy, so they may want to know more about the probability and severity of the side effects. It is recommended that "common chemotherapy side effects" be changed and the coach explain it in detail	Accept the modification: The mention of side effects will be changed to "common chemotherapy side effects" or "chemotherapy-like side effects" and will be explained in detail by the coach
4	The median overall survival in the untreated column is about 2 years. Since the number of collected patients is all patients who have not relapsed and are not divided into relapses within versus after 6 months, it is easy to confuse patients using this SDM, and the time to use this SDM should already be determined. After discussing with the doctor, the patient decided to undergo chemotherapy. It is recommended to delete the untreated column	Accept the modification: Delete the untreated field because it may confuse patients and affect their choice of the most suitable treatment method
5	Step 1 - you can link the consideration factors and tables with icons. For example, financial factors and required costs are marked with a copper plate (□) symbol to help patients more quickly assess their own priorities	Accept modification-consideration factors and corresponding tables are added with icon symbols to facilitate patient identification (1) Economic factors and required costs (2) Survival period and mOS (3) Quality of life and mPFS (4) Side effects
6	It is recommended that the considerations be moved to the front of the medical options form to help patients clarify their most important aspects and values and then read the medical options form to more quickly find their values	Modification is not accepted. Reason: icon assistance has been added. Maintaining the original steps after discussion will enable patients to better consider the advantages and disadvantages of treatment
7	The wording suggestions should be more colloquial to make it easier for patients to understand. For example, "treatment effectiveness" can be changed to "quality of life"	Accept modification: Consideration of oral language (1) Treatment effectiveness was changed to "quality of life"
8	More psychological support resources can be added	Accept modification: Add psychological support group QR code

SDM=Shared decision-making; mPFS=Median disease progression-free survival; mOS=Median overall survival; ORR=Objective response rate; QR=Quick-response

your level of anxiety (0–10 points) when facing current medical problems before and after SDM between doctors and patients?," the average anxiety score of the public testers decreased from 7.5 to 5 points after PDA use.

DISCUSSION

According to British Cochrane[10] empirical research, the use of decision-making aids can achieve the following results: (1) increase user knowledge of the selected items (high-quality evidence); (2) more informed and clear feelings about the relevant information (high-quality evidence); (3) increased accuracy of expectations about the possible benefits or harms of various choices (moderate-quality evidence); and (4) Greater participation in more decision-making processes (moderate-quality evidence).[11] These four results are consistent with the trends in the questionnaire feedback from assistive tool explainers (physicians) and recipients (public). The reduction in the anxiety level of public testers is speculated as positively correlated with these results.

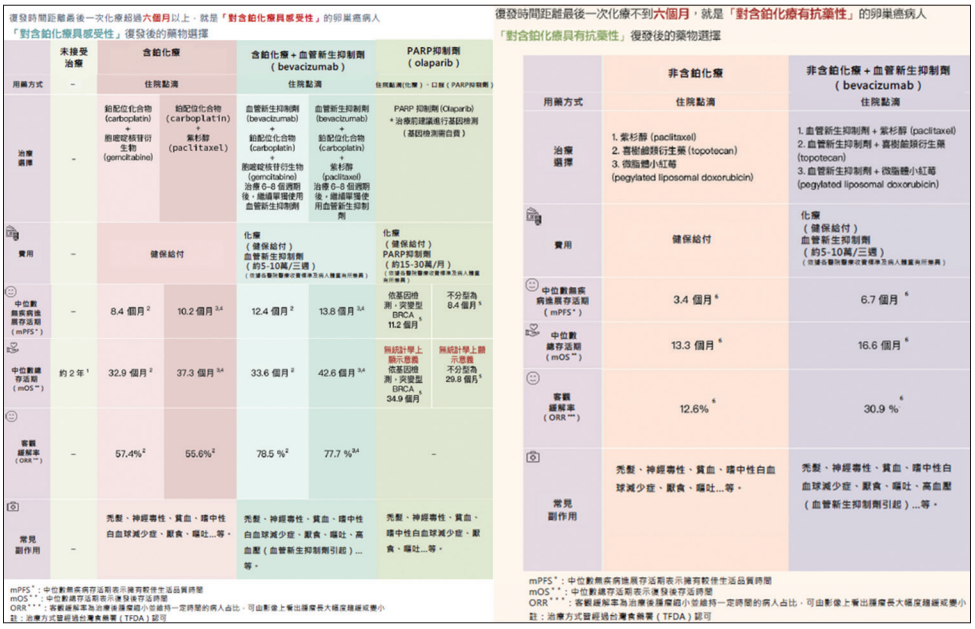

Figure 1: Patient decision aid: Shared decision-making tool for doctors and patients

Figure 2: Video of shared decision-making between a doctor and a patient with recurrent ovarian cancer choosing maintenance target drugs

Doctors and public representatives play crucial roles in the PDA development process. By soliciting feedback from clinical doctors in this field, we learned which clinical problems for which there are currently more than two reasonable options or for which there is no clear answer in empirical medicine. Auxiliary tools such as a PDA make it easier for patients to make the right decisions for them. This prevents waste of time and personnel due to inappropriate questions and will maximize the effectiveness of the PDA question selection, research, and development processes. With the participation of public representatives in the research and development process, we can discover what patients really care about when using it and identify the blind spots that medical staff may have. This can make the auxiliary tools more relevant to the explanations of the issues that the public cares about, thereby achieving a "patient-centered" approach.

In the entire PDA research and development process, the authors believe that literature preparation requires the greatest investments of manpower, time, and energy. To provide patients with the completeness and credibility of the evidence-based medicine evidence level of the treatment options they choose, in addition to searching the literature and reading much information, we must provide information about whether the drug's use is in line with local medical accessibility (e.g. Is this drug available in Taiwan?) and legality (e.g. Is this drug approved by the TFDA?) issues. For the question "How can the obtained information be used?," a large amount of information is organized into tables and diagrams that can be easily read and understood by the public. The information then becomes a document that can truly assist doctors and allow patients to easily understand currently available medical models.

In terms of how to organize important information into tables and diagrams that are easy for the public to read and quickly understand, the layout design and the artist role in PDA development are indispensable. Thanks to technology, by providing QR (quick-response) codes or website links with relevant information about the PDA, patients can use online resources to browse medical assistance videos recorded by the team [Figure 2; https://youtu.be/OGASHSgzjYA] as well as information about the relevant disease. Support groups and social supports are also available.

Follow-up medical decision-making aids continue to be optimized as follows. Technology and medical research are changing daily, and the original intention and purpose of the PDA is to present the latest medical literature and treatment options and provide doctors and patients with the latest and

most accurate information. It is hoped that this medical decision-making aid will provide patients with recurrent ovarian cancer with more concepts and increase their understanding to help them choose the best treatment method. Subsequently, the medical team can develop personalized treatment strategies and achieve smooth and good communication.

CONCLUSION

According to this newly developed PDA, doctors and the public play a pivotal role: the latest medical literature and treatment options are kept up with, and the most correct and updated information is provided for use by doctors and patients. Therefore, the PDA design's original intention and purpose were fulfilled.

Data availablity statement

The data that support the findings of this study are available from the corresponding author, Chuang-Yen Huang upon reasonable request.

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Conflicts of interest

There are no conflicts of interest.

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