

Background Ovarian Cancer

Ovarian cancer (OC) has the highest proportion of Stage III and IV upon diagnosis when compared to other cancers, making it one of the most fatal for women [1]. There are many risk factors associated with OC [2]:

- Older age: highest incidence between 60-64 years
- Ethnicity: white, Ashkenazi Jewish descent
- Lifestyle habits: diet, obesity, smoking
- Drug use: hormone replacement therapy (HRT), non-steroidal anti-inflammatory drugs, infertility drugs, talc
- Genetics: carrying *BRCA1* and *BRCA2* germline mutations, diagnosis of Lynch Syndrome

Despite this, mortality rates have declined 2% per year between 2004 and 2012, which can be attributed to the use of oral contraceptives, decrease in use of HRT, and general treatment and management improvements in this disease [3]. One treatment strategy is using the drug, Olaparib, a PARP inhibitor, which has been shown to be effective in treating platinum-sensitive, recurrent, serous OC with a *BRCA* mutation [4].

Consent for Genetic Testing

Genetic testing and screening for *BRCA* mutations that increase the risk for OC can be used for targeted treatments such as Olaparib and offer screening for relatives at risk. The BC Cancer Agency (BCCA) houses the Hereditary Cancer Program, which provides genetic counselling and screening for those who fulfill the testing criteria. Consent is required for *BRCA* mutation testing and traditionally has been done on a one-to-one basis; however group consenting seminars have the potential to accelerate this process.

Primary Study

The objective of the primary study was to determine whether the seminar model of consenting patients to *BRCA* testing was effective in decreasing wait times from diagnosis to test results and increasing the number of eligible OC patients completing testing [5]. The study utilized a retrospective approach via chart audits at BCCA from March 2014 to February 2018. The inclusion criteria were patients diagnosed with epithelial OC and exclusion criteria were patients with mucinous and borderline tumor.

These participants were divided into two cohorts:

- 1) Patients who were referred to *BRCA* testing pre-initiation of the consenting seminar, and
- 2) Patients who were referred to *BRCA* testing post-initiation of the consenting seminar, with
 - a) Participants *not attending* the seminar, or
 - b) Participants *attending* the seminar

Results

From April 2016 to February 2018, 90 patients attended the consenting seminar (81% of those eligible), to which 98% went on to complete *BRCA* testing. The majority of these patients in the post-seminar cohort had high grade serious OC with a *BRCA2* mutation status. The average time from referral to consenting seminar to *BRCA* testing was 92 days in seminar attendees vs. 176 days in those who did not attend (Table 1).

Table 1. Patient characteristics of the post-seminar initiation cohort.

	Non-Attendees (n = 21)	Attendees (n = 90)
Ovarian Cancer Subtype		
High grade serous	14 (67%)	79 (88%)
Carcinosarcoma	0 (0%)	3 (3%)
Endometrioid	2 (10%)	2 (2%)
Clear cell	5 (24%)	3 (3%)
Low grade serous	0 (0%)	1 (1%)
Other	0 (0%)	2 (2%)
BRCA Mutation Status		
<i>BRCA1</i>	0	3
<i>BRCA2</i>	2	5
<i>BRCA2 (VUS)</i>	0	2
Olaparib access	12	3
Average time from referral to seminar and BRCA report	176 days	92 days

The average wait time for the pre-seminar initiation cohort was 349 days whereas no patients in the post-seminar initiation cohort waited beyond 9 months for results. Those in the pre-initiation cohort most frequently waited 12-18 months for results while those in the post-initiation cohort received results within 3 months (Figure 1).

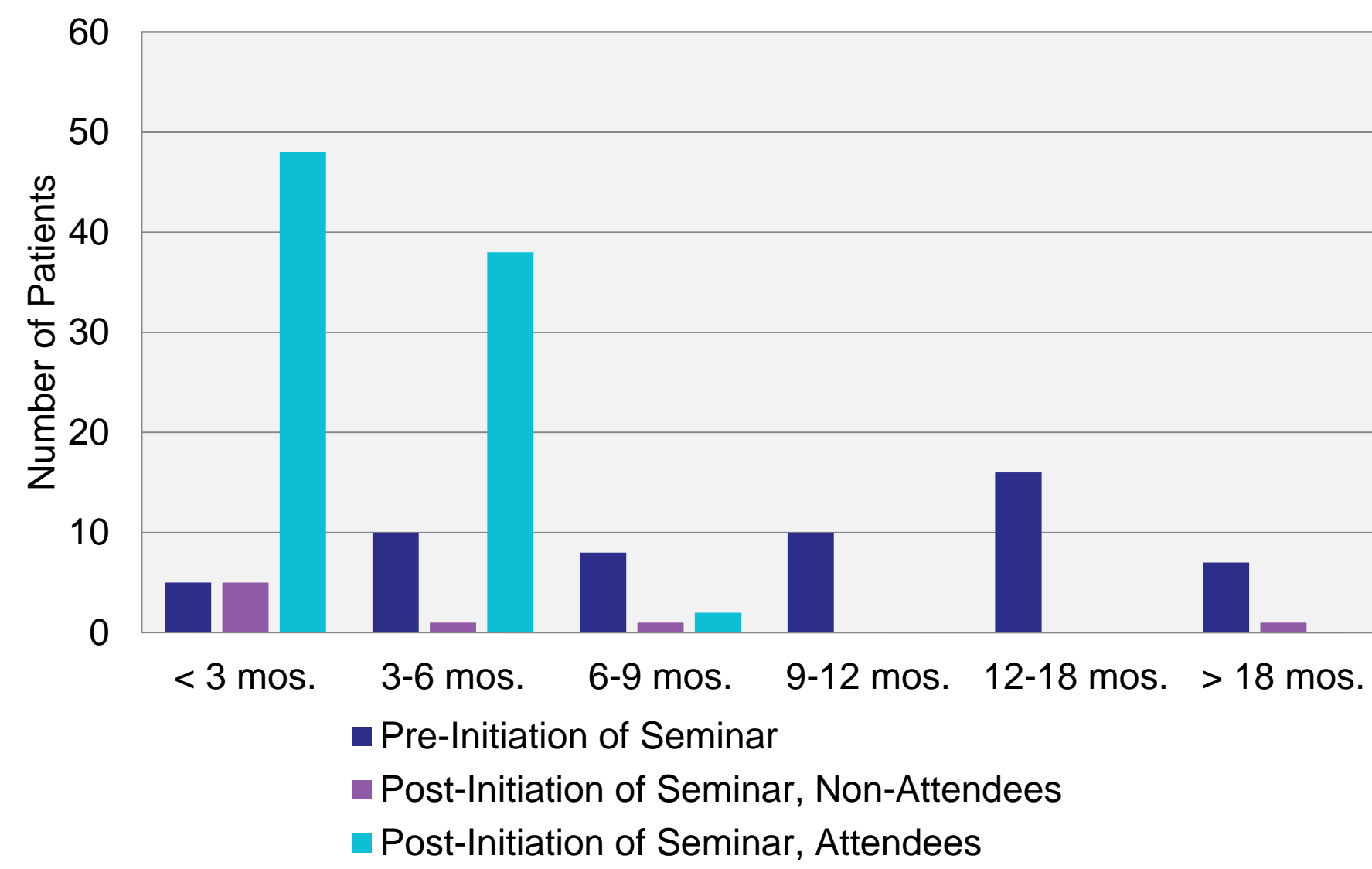


Figure 1. Time from referral to *BRCA* test result.

In the pre-initiation seminar cohort, 93/146 (64%) completed testing, resulting in 53 patients (36%) being lost to follow-up. In those who attended the seminar, 90 were eligible, 90 (100%) received referrals, and 88 (98%) completed *BRCA* testing. This is a marked improvement when compared to the post-initiation, non-attendee cohort, where 21 was eligible, 12 (57%) received referrals, and 7 (33%) completed testing (Figure 2).

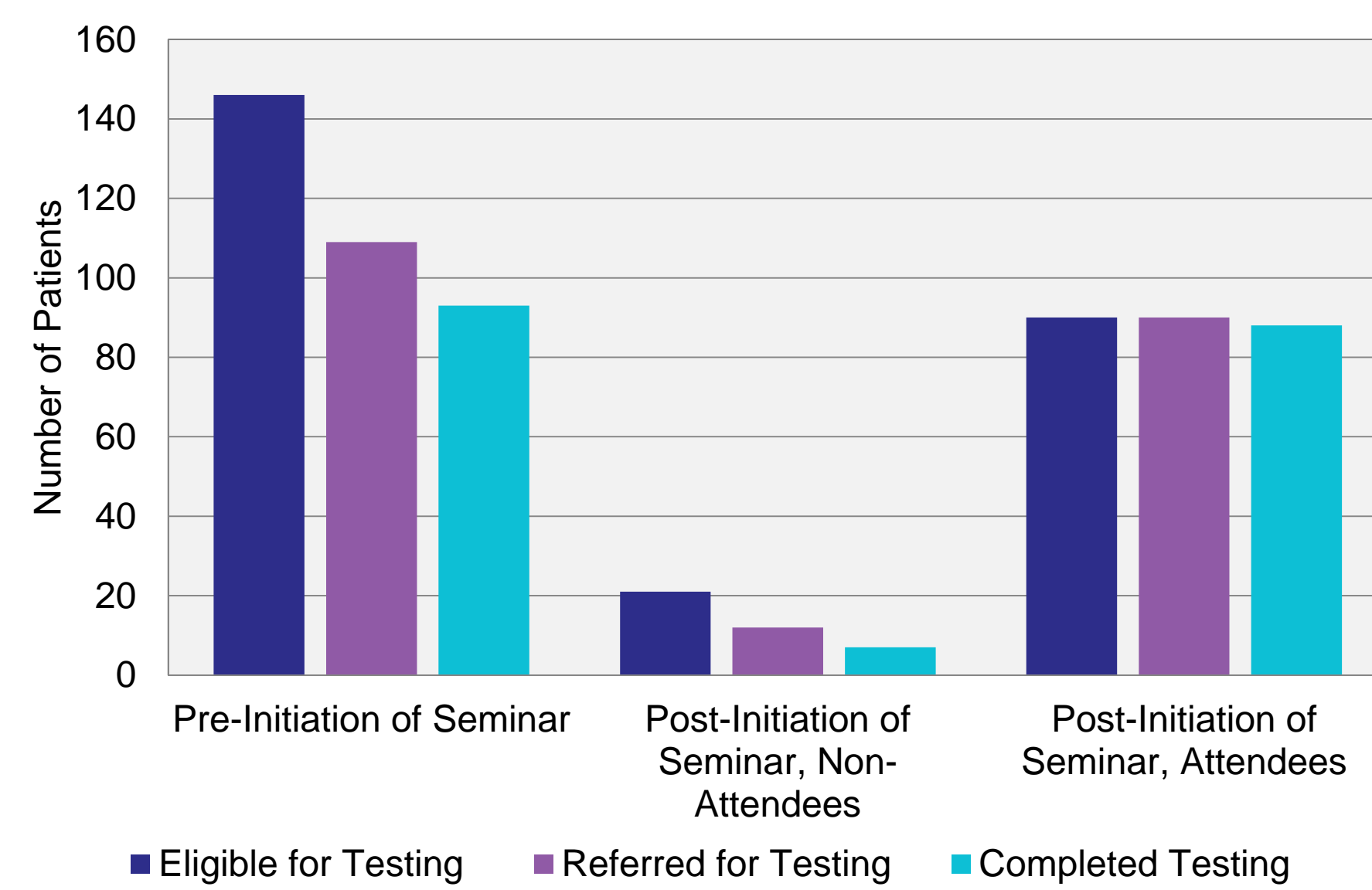


Figure 2. Patients undergoing *BRCA* testing.

Since May 2016, 49 patients have gained access to Olaparib. These findings demonstrate that the seminar model of consenting patients for *BRCA* testing decreases wait times from referral to test results and increases the number of eligible OC patients completing testing. This method offers an effective alternative to one-to-one appointments to obtain consent, which can then provide quicker access to genetic testing in those with OC.

Objective

The purpose of this sub-study is to determine patient-reported outcome measures (PROMs) in those with OC responding to a group seminar on genetic testing and consent delivered by a nurse practitioner (NP).

We hypothesize that participants will report high PROMs with the group education seminar model. These results would be congruent to the primary study's findings, which showed decreased wait times for test results, increased number of eligible patients tested, and allowed use of targeted treatments.

Literature Review

In November 2018, a literature review was conducted to determine what patient evaluation tool(s) were used in similar studies that investigated the topics of informed consent, group education, and patient education. The previous topics were used as search terms in the databases, Medline, Embase, CINAHL, PsychInfo, Google Scholar, and PubMed. With duplicates removed, 45 articles were reviewed, with 7 studies containing information pertinent to our sub-study.

In these 7 articles, it was found that the majority of the studies created their own evaluation tools and used no validated measure, such as surveys with 3- to 5-point Likert scales and informal interviews consisting of binary "yes or no" or "true or false" questions and open-ended questions. As other studies were being conducted at BCCA, the study team contacted other investigators for their evaluation tools in order to validate a tool designed to measure outcomes in a similar population and context.

Genetic Counseling Outcome Scale

The Genetic Counseling Outcome Scale (GCOS-24) is a 24-item questionnaire using a 7-point Likert scale ranging from "strongly disagree" to "strongly agree" to assess for PROMs for clinical genetics services [6]. Convergent and divergent validities, and sensitivity to change over time with a medium-to-large effect size has been shown to be within acceptable limits.

The GCOS-24 is currently being used at BCCA with group counselling sessions (Figure 3); therefore it is applicable for use in this sub-study.

Furthermore, another second literature review showed the GCOS-24 has been used in four other studies:

- Translated and adapted for use in Denmark [7] and Spain [8]
- Utilized in an exploratory study that investigated both the GCOS-24 and EQ-5D in supporting service quality improvement in clinical genetics [9]
- Assessed empowerment and support group participation in those with undiagnosed disease [10]

Questionnaire #1
The Genetic Counselling Outcome Scale (GCOS-24)

Using the scale below, circle a number next to each statement to indicate how much you agree with the statement. Please answer all the questions. For questions that are not applicable to you, please choose option 4 (neither agree nor disagree). We define the 'condition' here as your family history of cancer.

1 = strongly disagree
2 = disagree
3 = slightly disagree
4 = neither disagree nor agree
5 = slightly agree
6 = agree
7 = strongly agree

1	I am clear in my own mind why I am attending the clinical genetics service.	1	2	3	4	5	6	7
2	I can explain what the condition means to people in my family who may need to know.	1	2	3	4	5	6	7
3	I understand the impact of the condition on my child(ren) / any child I may	1	2	3	4	5	6	7

Figure 3. A sample of the GCOS-24 used at BCCA.

Ethics Application

The ethics application will be submitted through the University of British Columbia's Research Information Systems. The method will be a prospective study recruiting previous and current patients who have attended or will attend the group consenting seminar.

The inclusion criteria include patients over the age of 18 with OC that have or will attend the group consenting seminar, and is able to communicate and understand English in written or verbal forms. Exclusion criteria are those 18 years of age and younger with OC of low grade malignancy and mucinous subtype, and are unable to communicate or understand English.

Data records obtained from this study will be from the BC Cancer Registry, Cancer Agency Information System, referencing the primary study's parameters.

After obtaining consent from participants, the procedure will involve a NP, who is a researcher of this sub-study, to review the general premise of the GCOS-24. The NP will ask if the patient requires assistance in completing the tool and clarify any questions during the survey. Once the GCOS-24 has been completed, a quick debriefing session will be held to explore if the participant has any questions or concerns. At any time of the survey, the patient may withdraw consent from participating. There are no consequences to withdrawing from this sub-study and participants will not be reimbursed for their time.

Conclusion

The results of this sub-study will support the primary study in determining whether the group consenting seminar is an effective method for educating patients and obtaining consent through PROMs. This will be reflected by high PROM scores. These results can be used to inform clinical practice and health services, which could then improve patient needs and outcomes in those with OC. In addition, the combination of using the group consenting seminar and the GCOS-24 can further refine how current healthcare services provide genetic screening for families, which can give rise to an effective disease prevention strategy.

Acknowledgements

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