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Consensus in controversy: The modified Delphi method applied to Gynecologic Oncology practice

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HIGHLIGHTS

- The Delphi technique provides expert opinion when accurate data does not exist.
- The Delphi technique achieves consensus with multiple iterations of the same question.
- The Delphi technique is a useful tool for modeling studies.

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ABSTRACT

Objectives. To determine the degree of consensus regarding the probabilities of outcomes associated with IP/IV and IV chemotherapy.

Methods. A survey was administered to an expert panel using the Delphi method. Ten ovarian cancer experts were asked to estimate outcomes for patients receiving IP/IV or IV chemotherapy. The clinical estimates were: 1) probability of completing six cycles of chemotherapy, 2) probability of surviving five years, 3) median survival, and 4) probability of ER/hospital visits during treatment. Estimates for two patients, one with a low comorbidity index (patient 1) and the other with a moderate index (patient 2), were included. The survey was administered in three rounds, and panelists could revise their subsequent responses based on review of the anonymous opinions of their peers.

Results. The ranges were smaller for IV compared with IP/IV therapy. Ranges decreased with each round. Consensus converged around outcomes related to IP/IV chemotherapy for: 1) completion of 6 cycles of therapy (type 1 patient, 62%, type 2 patient, 43%); 2) percentage of patients surviving 5 years (type 1 patient, 66%, type 2 patient, 47%); and 3) median survival (type 1 patient, 83 months, type 2 patient, 58 months). The group required three rounds to achieve consensus on the probabilities of ER/hospital visits (type 1 patient, 24%, type 2 patient, 35%).

Conclusions. Initial estimates of survival and adverse events associated with IP/IV chemotherapy differ among experts. The Delphi process works to build consensus and may be a pragmatic tool to inform patients of their expected outcomes.

1. Introduction

The standard treatment for advanced ovarian cancer is surgical cytoreduction followed by cytotoxic chemotherapy. While the mainstay

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for adjuvant chemotherapy has been treatment with intravenous (IV) platinum and taxane agents, several phase III clinical trials have demonstrated improved survival with the use of these drugs both IV and intraperitoneally (IP) [1]. Consistent positive results from these studies led to a National Cancer Institute clinical announcement [2] in 2006 supporting the use of IP chemotherapy in selected patients with advanced ovarian cancer following cytoreduction with limited residual disease. The NCI announcement stated that patients "…should be counseled about the clinical benefit associated with combined IV and IP administration of chemotherapy". Despite this statement from the NCI, the use of IP chemotherapy has not become widespread, either by gynecologic oncologists or by medical oncologists [3,4], mainly due to the perception of increased toxicity and complexity of administration compared with IV chemotherapy. An additional reason for the lack of acceptance of IP chemotherapy may be clinician bias against this treatment strategy. This bias may have far-reaching implications, since recent literature indicates that the survival advantage of IP/IV over IV chemotherapy extends beyond 10 years [5]. Therefore, although patients and clinicians may differ in the perceived benefits of treatments, as well as the most important treatment-related side effects [6,7], it is reasonable to open the IP versus IV discussion through a shared decision-making model.

The Affordable Care Act Section 3506 is a "program to facilitate shared decision making" whose purpose is to "facilitate collaborative processes between patients, caregivers or authorized representatives, and clinicians that engages the patient, caregiver or authorized representative in decision making, provides patients, caregivers or authorized representatives with information about trade-offs among treatment options, and facilitates the incorporation of patient preferences and values into the medical plan." In an effort to enhance the process of shared decision making regarding the route of administration (IV versus IP/IV) of chemotherapy in women with advanced ovarian cancer, we developed a decision aid using estimates of clinical parameters from the literature and from completed and ongoing phase III randomized clinical trials of IV versus IP/IV chemotherapy. Given the differences between populations enrolled in clinical trials and those seen in general practice, we sought to determine the degree of professional consensus regarding the probabilities of specific patient outcomes associated with IV and IP/IV chemotherapy. We administered a web-based survey to an expert panel of clinicians, using the modified Delphi method, described below, to obtain consensus in ovarian cancer patient outcomes that would be expected in usual practice. This technique allows clinicians to base their decisions and responses on more then just their own experience in their own practice, but rather to benefit from the additional experience of a larger community of clinicians.

2. Methods

As part of a PCORI-funded project, 10 ovarian cancer experts (9 gynecologic oncologists and 1 medical oncologist) who administer both IV and IP/IV chemotherapy were asked to provide estimates pertaining to four process or outcome events for two hypothetical patients. They were asked to provide these probabilities for each of the patients and each of the four processes or outcomes, one assuming the patient received IV chemotherapy, and one assuming the patient received IP/IV chemotherapy. In this setting, an expert is defined as a board-certified clinician who has been involved in the chemotherapy management of ovarian cancer for over five years, and who has a willingness to prescribe both IP/IV and IV therapy for advanced ovarian cancer for their patients. They were further selected based on their strong records of clinical trial participation, and representation across the country from both rural and urban settings (which was intended to allow for diversity of responses based on geographic and clinical variation. Experts all practiced at academic medical centers. The purpose of this definition of expertise was to maximize the likelihood that experts were highly knowledgeable regarding the outcomes and toxicities associated with both modes of chemotherapy administration. The regimens and schedules used for IP/IV and IV chemotherapy were not explicitly defined in an effort to allow for responses patterning what is seen in usual practice (for example, with some patients being given bevacizumab or weekly paclitaxel). Experts were queried on the outcomes of two "types" of patients: "type 1" was a patient with limited comorbidities, with a performance status of 1 (prior to initiation of chemotherapy but after cytoreduction) and who underwent complete cytoreduction without bowel resection; "type 2" was a patient with moderate comorbidities, with a performance status of 2 (prior to initiation of chemotherapy but after cytoreduction) and who underwent an optimal cytoreduction with small volume residual disease requiring rectal resection with anastomosis. The panel was asked to provide estimates for the following four events: 1) probability of ER/hospital visits during chemotherapy treatment, 2) probability of completing 6 cycles of the prescribed chemotherapy, 3) probability of surviving 5 years, and 4) median overall survival time (Table 1). The survey was administered in three rounds. Subsequent to round 1 and round 2, a summary of responses and individuals' anonymous explanatory comments were circulated back to the panel, and the experts were asked to resubmit their probability estimates in light of the (anonymous) replies of other members of the panel.

This methodology is known as the Delphi survey technique [Fig. 1], which was developed in the 1950s by research scientists working at the RAND Corporation [8]. The original Delphi technique provided open-ended questions; modifications of this technique as used in this study (known as the modified Delphi technique) allow for the process to begin with a set of carefully selected items drawn from various sources (including synthesized reviews of the literature, and interviews with selected content experts). The modified Delphi strategy provides a highly structured, transparent process to obtain anonymous feedback. The approach allows participants to reassess their own judgments as recommendations which are revised according to feedback received through the process. In addition, quantitative data can be collected, allowing for the application and reporting of statistical analyses [9]. Through a series of rounds (typically three), the process is designed to yield consensus. The anonymity of the expert panel is maintained throughout this process to prevent the authority, personality, or reputation of some participants from dominating others in the process. Anonymous participation also allows free expression of opinions, encourages open critique, and facilitates admission of errors when revising earlier judgments [10,11].

Responses from the experts were summarized using descriptive statistics (mean, median, standard deviation, range) for each patient type, treatment, and outcome after each of the three Delphi surveys. Power analysis and statistical significance are appropriate only for studies that test a hypothesis; these do not apply to descriptive studies such as the Delphi technique. Responses were also examined graphically to identify outliers. Optional comments provided by the experts following each round enabled revision of questions for improved clarity and greater consensus at subsequent rounds.

3. Results

Administration of the survey to 10 ovarian cancer experts who utilize both IV and IP/IV chemotherapy in their practices was performed in three rounds. In the first round, experts estimated that patients undergoing IV chemotherapy had a lower probability of requiring a hospitalization or emergency department visit compared to patients receiving IP/IV

Table 1
Questions posed to expert panel regarding IV versus IP/IV chemotherapy for advanced ovarian cancer.

1. Probability of ER/hospital visits during treatment
2. Probability of completing six prescribed cycles of chemotherapy
3. Probability of surviving 5 years
4. Median survival time