Practice challenges affecting optimal care as identified by US medical oncologists who treat renal cell carcinomas

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Background Approval of new agents provides alternative treatment options for medical oncologists and their patients with renal cell carcinoma (RCC). Treatment decisions remain challenging in the absence of clear evidence supporting optimal selection and sequencing of treatment for different patient or tumor characteristics.
Objective To assess the clinical practice gaps of medical oncologists treating patients with RCC.
Methods Medical oncologists practicing in the United States with a case load of 1 or more RCC patient(s) a year were recruited to participate in either an online case-based survey followed by a 45-minute interview (phase 1) or a 15-minute online survey with case vignettes (phase 2). Respondents' answers were compared with treatment guidelines and faculty experts' recommendations.
Results Qualitative interviews (n = 27) and quantitative surveys (n = 142) were compiled. Clinical performance gaps demonstrating oncologists' difficulties to optimally adjust their treatment plan were identified. When presented with an RCC patient with treatment-related hypertension, 34% of respondents did not select an expert-recommended option. In a scenario focused on recognizing clinical signs and symptoms as an important component of treatment decision-making, 40% of respondents agreed with the expert-recommended approach. For a progressive patient with chronic obstructive pulmonary disease, 78% of respondents were misaligned with evidence-based treatment options.
Limitations Self-selection and respondent bias may have occurred. Sample size may have limited the statistical power.
Conclusions This study identified clinically relevant performance gaps among US oncologists treating RCC patients. Education to assure familiarity with the most recent changes is needed.
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Renal cell carcinoma (RCC) had long been considered a cancer resistant to therapy, with few therapeutic options beyond surgery.[1,2] In recent years, several new agents with better efficacy and safety profiles have been approved for advanced RCC.[2-4] Although the new agents can greatly improve patient quality of life and health outcomes, nothing is known about the best choice of a first agent, the optimal sequence of agents and optimal combined use of those agents in advanced RCC, and any potential role of the agents as adjuvant therapy after surgery. In addition, there is little guidance for the therapy decisions for certain patient profiles, such as patients with comorbidities.[5,6] Physicians, particularly oncologists, face a multitude of barriers in overcoming the challenges of staying current in a rapidly changing field, which creates an ongoing educational/professional practice gap in this field.[1] Previous data indicate that there are many educational needs and practice gaps among oncologists, as illustrated by the uncertainty about the optimal treatment and management of RCC.[7,8]

In areas where clear clinical guidelines have not been established or are evolving rapidly, expert recommendations can become an important source of validation for treatment plan decisions for oncologists. This study aims to assess the clinical practice gaps among medical oncologists in the US as they provide care to patients with RCC, by comparing their reported current practice with evidence-based or expert-supported recommendations for optimal care in the field.

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Methods

Study design

This assessment integrated the collection and analysis of qualitative and quantitative data in a mixed-methods procedure, whereby an initial qualitative exploratory phase informed a subsequent quantitative confirmatory phase.[9] The approach draws upon the strengths of each method: the depth of qualitative data and the analytic power of quantitative data collection.[10] Triangulation of approaches (qualitative, quantitative) and of data collection methods (interviews, survey) was used to increase the validity and trustworthiness of findings.[11,12]

Ethical approval

Two distinct independent ethical approvals (IRB Services for qualitative phase and Eisenhower Medical Center Institutional Review Board for quantitative phase) were obtained to ensure informed consent, confidentiality of participants, ethically acceptable level of compensation (ie, market fair, but not enough to create coercion), and respect of national guidelines and policies for data protection and data storage.[13]

Tools design and data collection

The co-authors conducted a review of published literature and internal data to generate hypotheses on the gaps in knowledge, clinical skills, and confidence of US oncologists who are providing care to patients with RCC. The hypotheses that were generated were used to inform the design of a case-based survey and a qualitative interview guide for the conduct of semistructured telephone interviews.

Cases were designed by coauthors Thomas E Hutson and Brian Rini, both nationally recognized experts in RCC, with support from other coauthors. Case-based questions have been demonstrated to be a valid method to investigate potential clinical practice gaps.[14] The cases used for the qualitative and quantitative phases were similar (although the qualitative cases were presented in ways that made them more iterative).

The semistructured telephone interviews focused on the challenges experienced by the provider as they answered the case-based questions. Interviews also leveraged the cases to address the personal, contextual, and behavioral factors, above and beyond clinical guidelines, evidence, and/or standards of care that can influence a provider's clinical reasoning process. With the consent of participants, interviews were audio-recorded for transcription and analysis. An interviewer's debriefing session was conducted with all other interviewers present to generate in-depth discussion around the emerging themes.

Findings from the qualitative phase as well as information gathered in the initial literature review process were used to inform the design of a 15-20–minute quantitative survey that was used in phase 2 of the study. The survey consisted of multiple choice questions, semantic differential rating scale questions, and case vignettes. The full survey is provided online (Supplementary File 1).

Recruitment and inclusion criteria

Invitations to participate in both phases of the study were e-mailed to a list of 11,696 medical oncologists who are members of Clinical Care Options. Invitations included a Web link where interested participants could learn about the study, sign a consent form, and answer prescreening questions so that we could determine their eligibility.

A purposive sampling method (combining criterion sampling and maximum variation sampling) was used to ensure recruitment of oncologists with a mix of gender, years of practice, and practice setting into the study.[15] To be eligible to participate in the qualitative phase, participants had to be actively practicing in oncology and have a case load of at least 5 patients with RCC per year. Inclusion criteria for the quantitative phase were the same as those of the qualitative phase with the exception that the caseload was reduced to a minimum of 1 patient per year to also allow for identification of challenges and clinical gaps in the group of practitioners that may be most unfamiliar with RCC.

Analysis plan

A subset of interviews was transcribed, coded, and analyzed using NVivo qualitative data analysis software (QSR International Pty Ltd, Version 7, 2006). The qualitative analysis approach used included 4 steps:

- Identification of a coding logic (or coding tree), with predetermined codes based on the domains of exploration that were being investigated.
- Coding of data using coding logic.
- Analysis of data that could not be coded using the coding tree and addition of new codes if needed.
- Identification of emerging specific themes from the codes with substantial data.
- This approach is derived from principles of both thematic analysis[16] and directed content analysis.[17]

The data collected from the online cases in the first phase of the study and from the quantitative survey in the second phase were analyzed using SPSS 12.0 software (SPSS, Chicago, IL). To identify gaps in respondents' practice, answers to the quantitative survey were compared with optimal or acceptable answers (as identified by treatment guidelines[18,19] and faculty experts). Triangulation of qualitative and quantitative data allowed for identification of the most important gaps and inference of potential causalities to those gaps. Subgroup differences (by years of practice, practice types, or caseload) were calculated when means could be calculated Pearson's chi-square test for nominal variables (ie, multiple choice questions).

Results

Sample size and demographics

For the initial phase of the study, 41 potential participants filled in the screener, and 27 met the eligibility criteria and were recruited for qualitative interviews. For the quantitative phase, 207 participants provided informed consent and began the quantitative online survey. Of those, 65 participants either did not meet the eligibility criteria or had incomplete demographic data, leaving a total of 142 participants to be included in the analysis. Table 1 presents the details of the demographic information for the study sample.

The participants were experienced clinical practitioners, with most (40%) having more than 20 years of practice experience. The sample represents a variety of practice settings, with academic medical centers (37%) and group practices (30%) being the predominant subgroups. Participants in the qualitative sample had fewer years of experience but a greater caseload of patients with RCC compared with the quantitative sample. The 2 samples were otherwise similar in their distribution of the demographic variables.

Identified practice performance gaps

Several key practice performance gaps were identified from the triangulation of qualitative and quantitative data (the list of gaps is provided online, Supplementary File 2). Additional analysis and interpretation of those gaps by the coauthors indicated a number of the gaps were indicative of medical oncologists' difficulties to optimally adjust their treatment plan when faced with certain patient responses or characteristics. These would be the focus of this article. Qualitative quotes illustrating these findings are online (Supplementary File 3).

Dose continuation in the presence of treatment-related side effects. When the participating oncologists were presented with the case of a patient with treatment-related hypertension who was unresponsive to single/initial antihypertensive therapy, 34% of them chose a management option that was not recommended by faculty experts (Table 2, Q6). In particular, 17% of respondents opted for an unnecessary reduction in current treatment dose in the presence of treatment-related hypertension. There were no differences in response by experience, case load, or clinical setting.

In the case of treatment-related hypertension, 14% of participating oncologists would refer to a cardiologist. Most said they would maintain the dose and manage the hypertension themselves. Accounts from the qualitative interviews indicate that the decision to manage the problem by themselves versus referring to another specialist depends on the severity of the hypertension, the patient's renal function, the patient's insurance status, and the oncologist's comfort with using various classes of antihypertensive agents. Access to a cardiologist was also reported by participants as a referral barrier. Additional survey questions asked the participants to rate, on a scale of 1-7 (1 = consistent/easy access, 7 = no access), the level of access to different providers they had in their practice. Access to a cardiologist was rated as 4 or above by 40% of participants (data not shown).

Dose escalation for patients responding to treatment. When presented with a case of a patient with "good-risk" RCC treated with axitinib for 4 weeks with no progression, no elevated blood pressure, and no adverse events, most of the participants (61%) reported they would continue therapy at current dose (Table 2, Q7). The evidence-based answer supported by faculty recommendation was continuation of axitinib at an elevated dose (selected correctly by 27% of the respondents). Respondents with a higher yearly caseload were significantly more likely to select the recommended option than were respondents with a smaller caseload – 50% of participants with caseload of more than 20 patients a year selected the recommended answer, compared with 20% and 23% for 1-4 and 5-20 patients, respectively). Respondents' answers were not significantly correlated with years of clinical experience or practice setting. Interview responses indicate that the new evidence supporting dose escalation of certain agents for a patient with good response to a treatment regimen seems counterintuitive to practicing oncologists.

Treatment adjustments in a patient with no clear sign of radiologic progression. When presented with the case of a patient treated with pazopanib with increased alanine aminotransferase and bilirubin but no clear signs of radiologic progression, 40% of participants selected 1 of the 4 possible options endorsed by the expert faculty: switch to axitinib (19%), everolimus (8%), sorafenib (2%), or sunitinib (11%), as shown in (Table 3, Q8). The answer that was most frequently selected by respondents (22%) was to discontinue treatment. Continuing treatment with pazopanib until clear progression was selected by 11% of the respondents, although it was not a faculty-recommended option. Respondents with fewer years of experience (10 years or less) were significantly more likely to endorse a recommended answer than were respondents with more experience (10 years or more; 44% vs 23%; chi-square, $P = .030$). There were no differences by case load or practice setting.

Another case presented a progressing patient with a comorbid condition (chronic obstructive pulmonary disease), for whom 78% of the respondents did not provide the optimal, faculty-supported answer (treat with pazopanib; Table 3 Q9). The respondents' answers were distributed almost equally among all of the alternative answers. Sunitinib and temsirolimus were chosen by 20%

TABLE 1 Recruitment and eligibility, sample distribution and respondents' characteristics for both study phases

	Recruited	Ineligible or missing information	Analyzed sample
Qualitative	41	14	27
Quantitative	207	65	142
Total	248	79	169

	Qualitative (n = 27)		Quantitative (n = 142)		Analyzed sample (n = 169)	
Years of practice	n	%	n	%	n	%
≤ 10	18	66.7	45	31.7	63	37.3
11-20	4	14.8	40	28.2	44	26.0
> 20	5	18.5	57	40.1	62	36.7
Practice setting						
Academic medical center	9	33.3	52	36.6	61	36.1
Government hospital	1	3.7	6	4.2	7	4.1
HMO/managed care	0	0.0	3	2.1	3	1.8
Hospital system	2	7.4	15	10.6	17	10.1
Group practice	10	37.0	42	29.6	52	30.8
Non-affiliated community or small private hospital	2	7.4	6	4.2	8	4.7
Solo practice	2	7.4	15	10.6	17	10.1
Other	0	0.0	3	2.1	3	1.8
Did not answer	1	3.7	0	0.0	1	0.6
Percentage of caseload being RCC						
0-1	0	0.0	3	2.1	3	1.8
> 1-10	19	70.4	130	91.5	149	88.2
More than 10%	8	29.6	8	5.6	16	9.5
Did not answer	0	0.0	1	0.7	1	0.6
Number of RCC patients per year						
1-4	0	0.0	30	21.1	30	17.8
5-20	13	48.1	88	62.0	101	59.8
More than 20	14	51.9	24	16.9	38	22.5

HMO, health maintenance organization; RCC, renal cell carcinoma

and 13% of respondents, respectively, but were not recommended by expert faculty. Responses were not significantly related to experience, practice setting, or case load.

Factors affecting decision of a treatment plan

After completing each case, participants in the qualitative interviews discussed factors they take into account to determine their treatment selection. The most frequently reported factors were patient comorbidities, age and general physical condition, MSKCC score (likelihood of nonrecurrence at 5 years after surgery), prognostic factors, potential treatment side effects, patient preferences, and the participant's own experience with a given therapeutic agent (data not shown).

Participants were also asked to comment on the factors that may influence their decision to choose one treatment over another in a given situation. Previous experience with a drug was one of the factors reported most often as influencing the selection of treatment. Other external factors that were mentioned included treatment reimbursement by the patient's insurance plan. Using data from clinical trials on recently approved agents was mentioned as

TABLE 2 Case-based questions related to dose continuation/escalation due to patient response[a]

Q6. How do you manage patients with advanced/metastatic renal cell carcinoma who develop treatment-related hypertension that does not resolve with a single/initial antihypertensive treatment?		
Selected answer (n = 137)	n	%
A. Maintain dose/schedule; refer to cardiologist for further management	19	13.9
B. Maintain dose/schedule; initiate second antihypertension agent	72	52.6
C. Reduce dose of treatment agent	23	16.8
D. Stop treatment	4	2.9
E. Switch to a new agent	8	5.8
F. Adopt 'a wait-and-see' approach	6	4.4
G. Unsure	5	3.6
Comparison of Q6 responses with faculty's answers		
Selected 1 of the 2 optimal answers	91	66.4
Selected 1 of the nonoptimal choices	46	33.6
Q7. For a patient with 'good-risk' metastatic renal cell carcinoma who was treated with axitinib for 4 weeks and has no signs of progression, no increase in blood pressure, and no adverse events, what would you recommend in terms of these options?		
Selected answer (n = 141)	n	%
A. Continue treatment with axitinib at its current dose	86	61.0
B. Continue treatment with axitinib, but escalate dose	38	27.0
C. Discontinue treatment with axitinib and switch to another agent	4	2.8
D. Pause treatment with axitinib; restart when progression is detected	4	2.8
E. Unsure	9	6.4

[a] Shaded answers are expert recommendations.

challenging by participants, because there are few head-to-head comparison studies available to facilitate the selection of an optimal choice. Patients with comorbidities are often excluded from clinical trials, although they constitute a large proportion of the patients encountered in practice (see illustrative quotes online, Supplementary File 3).

Treatment adjustment to account for quality of life

Findings indicate that the challenge in establishing the best possible treatment plan lies in the sum of factors that need to be considered to be able to offer the most benefit without compromising the patient's quality of life (QoL). When the participants were asked how they went about assessing quality of life, most reported that they did not use any particular tool for that purpose. The definition of QoL varied greatly between respondents, from dealing with symptoms such as pain and fatigue, to maintaining employment or being able to perform daily activities (see supplementary online information). Data indicate that the lack of a clear definition and assessment strategies creates a challenge when trying to monitor changes in QoL, and when trying to adapt treatment decisions to account for a patient's QoL.

Discussion and conclusions

The treatment and management of RCC is uncertain and challenging to practicing oncologists because of several interrelated factors, including the variety and complexity of patient presentations, the large number of new agents being approved for use in RCC in recent years, and a relative lack of evidence to support some treatment decisions. Often, a variety of options could be considered reasonable in complex patient cases. For this reason, this study compared participants' choices, when applicable, with all optimal or reasonable options that could be selected, given current evidence.

Recent clinical evidence supports the option of escalating the dose of axitinib when a patient with "good-risk" metastatic RCC has no signs of progression and no adverse events.[20] A number of oncologists who participated in this study are not using the most recent clinical trial results to determine when escalating the dose would allow them to achieve an improved response with their patients with RCC. Participants may underestimate the difference in efficacy if the dose of axitinib is not adjusted based on the toxicity experienced by the patient. Having a better understanding of the large variation between individuals in the pharmacodynamics of axitinib as suggested by recent

TABLE 3 Case-based questions related to treatment adjustment in the presence of nonradiologic progression[a]

Q8. A 65-year-old woman with clear-cell RCC is diagnosed with metastases to the liver by computed tomography scan, 2 years postnephrectomy. She is assessed as MSKCC[b] good risk. After 2 months of treatment with pazopanib, her alanine aminotransferase and bilirubin concurrently increase to 4 and 3 times the upper limit of normal, respectively, but there is no clear sign of radiologic progression. What action do you take regarding her treatment?		
Selected answer (n = 140)	n	%
A. Continue pazopanib until clear progression	15	10.7
B. Switch to axitinib	26	18.6
C. Consider a clinical trial	8	5.7
D. Switch to temsirolimus	12	8.6
E. Switch to everolimus	11	7.9
F. Switch to sorafenib	3	2.1
G. Switch to sunitinib	16	11.4
H. Offer palliative therapy only	2	1.4
I. Stop treatment	31	22.1
J. Unsure	16	11.4
Comparison of Q8 responses to Faculty's answers		
Total of acceptable choices for Q8	56	40.0
Q9. For a 70-year-old patient with metastatic RCC, hemoglobin level of 9.5 g/dL, and an ECOG-PS[c] of 2 due to shortness of breath from chronic obstructive pulmonary disease resulting from a history of heavy smoking, what would be your choice of therapy at this stage?		
Selected answer (n = 142)	n	%
A. Axitinib	11	7.7
B. Temsirolimus	18	12.7
C. Everolimus	16	11.3
D. Pazopanib	31	21.8
E. Sorafenib	7	4.9
F. Sunitinib	28	19.7
G. Bevacizumab/interferon	5	3.5
H. High-dose interleukin (IL)-2	2	1.4
I. No treatment	8	5.6
J. Unsure	16	11.3

[a] Shaded answers are expert recommendations. [b]The [Memorial Sloane-Kettering Cancer Center] MSKCC score predicts the likelihood of nonrecurrence of RCC at 5 years after surgery. [c]Eastern Cooperative Oncology Group Performance Status Scale (ECOG PS) is a method for assessing the functional status of cancer patients.

clinical trial results can prompt medical oncologists to favor the treatment decision to increase the dose in patients who have not experienced adverse events.

Data from this study also indicate that some medical oncologists are challenged in identifying pazopanib as an optimal management approach for a patient with RCC who has increased alanine aminotransferase and bilirubin but no clear signs of radiologic progression. This may be a consequence of a gap we previously identified with regard to medical oncologists' use of inappropriate criteria for evaluating disease progression without considering patient's overall clinical symptoms as recommended by expert opinion.[21] Furthermore, a quarter of study participants inappropriately chose dose reduction or therapy discontinuation over maintaining the dose while ensuring the management of hypertension. Learner data from past educational activities show that 65% of physicians would inappropriately choose dose reduction or therapy discontinuation over supportive care for a patient with metastatic RCC experiencing moderate treatment-related adverse effects.[21]

Currently, there is insufficient experimental data on toxicity management specific to RCC patients, therefore it is recommended that physicians manage treatment-related adverse effects using supportive care and pharmacologic interventions for the general population, reserving dose reduction or discontinuation only for patients with severe toxicities.[22] A recent evaluation of practice patterns in 18 US community oncology clinics indicated that

community-based oncologists were more likely than were oncologists in tertiary care centers to recommend treatment modification or discontinuation because of adverse events.[23] We did not observe a difference in inappropriate recommendations of dose modification or discontinuation by practice setting in our sample. This may be owing to a different segmentation of practice settings between the 2 studies, as our sample consisted of over 40% of oncologists in either group or solo practice or within small, nonaffiliated or private hospitals. Inappropriately choosing to reduce a dose or discontinue treatment may have a negative impact on the clinical outcome of patients with metastatic RCC. In addition, the number of participants who would refer to a cardiologist when faced with treatment-related hypertension that was unresponsive to initial antihypertensive treatment was low, which may be explained by the reported lack of access to those specialists.

For most metastatic RCC patients today, the goal of therapy is to prolong survival as long as possible while maximizing patient QoL.[24] The availability of new treatments adds complexity to the clinical decision making of medical oncologists when they are faced with a treatment that seems to offer great benefits but is associated with a particular profile of adverse effects that may impact QoL.[3,25] Among the factors that influence a practicing oncologist's preference for a given treatment plan, is his/her previous clinical experience with a specific drug regimen and its side-effect profile. This factor, along with the fact that new treatment options may not be reimbursed by insurance, may contribute to reducing the pace at which new drugs with supportive evidence are being implemented into practice. Finally, this study indicates that oncologists are not fully confident in their ability to assess and monitor QoL, and are challenged in considering QoL when evaluating the risk–benefit ratio of a possible treatment. Having a clear definition of QoL, which is shared by the patient, may help the physicians propose the best treatment options suitable for each patient.

This study shows a general lack of consistency in treatment decisions by medical oncologists compared with available evidence-based options, expert opinion, or practice guidelines. In most cases, these differences are not associated with their level of experience in the field or their case load of patients with RCC. Our sample consisted of a majority of medical oncologists who treat 5-20 cases of RCC a year, which represented 1%-10% of their overall patient case load. That range is likely to be similar to what most practicing US oncologists would encounter in their practices, given current prevalence rate for RCC. Thus we believe that the findings from this study can be generalized to the overall community of US practicing oncologists.

New agents are also becoming available for other tumor types. When most of their practice involves other tumor types, oncologists may have to prioritize the domains in which they decide to maintain their knowledge base. Acknowledging this reality, the opportunity therefore lies in providing practicing oncologists with easy to use tools that help them individualize their treatment according to the individual's tumor and patient characteristics. Such tools have been developed and tested and offer promising results.[5]

Overall, these findings suggest that patients with RCC, a complex disease for which many factors are weighed in clinical decision-making, may not receive the optimal treatment. Consequently, these patients may be subjected to unnecessary and avoidable medication side effects, receive drugs that do not fit their preferences, or that are not optimally adjusted to their individual profiles.

Limitations

This study methodology was based on self-report, which could be affected by respondent bias. Self-selection bias is also a possibility, as participation in the study was voluntary. A purposive sampling and triangulation methodology were used to limit such bias.

A subset of participants from which we did not have the complete demographic information was removed from the analysis. This analysis on a smaller sample may have limited the power to detect significant between group differences.

This study used cases to prompt participants on their current practice. However, when faced with a real patient and confronted with a diagnosis that they have not treated in some time, it is likely medical oncologists would seek out education to help them make the optimal decision. Findings from this study therefore highlight the fact that medical oncologists are not familiar with the current evidence or expert-recommended options, but does not imply that patient care is impacted by this lack of knowledge. Finally, given that the goals of this assessment were to identify gaps, challenges and barriers to optimal care in RCC, less attention was given to numerous areas in which care was excellent.

This study highlights the complex nature of decision-making in RCC and identifies clinically relevant performance gaps in a sample of practicing oncologists in the US. Those gaps can affect patients' access to optimal care, clinical efficiencies, and patients' quality of life and/or survival rates. Because RCC is an area in which evidence is evolving rapidly and clear clinical guidelines have not yet been established, medical oncologists, especially those who seldom see patients with RCC, could greatly benefit from opportunities to learn through continuing education activities, meeting with experts or gaining easier access to expert opinions and practice tools that can support their treatment plan decisions. These findings could also inform health care administrators in cancer centers interested in

developing performance improvement interventions at an organizational level. By validating the presence of these practice gaps in their own setting and bringing forward interventions aimed at bridging these gaps, they could help their professional staff provide better care to their patients in effective and efficient ways that also benefit the organization and the health care providers through enhanced professional fulfillment.

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