Advanced Prostate Cancer in Large Group Practices

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David Albala: Today I'm joined by Dr. Gary Kirsh, Past President of LUGPA, and Dr. Neal Shore, current President of LUGPA, who will share their insights into advanced prostate cancer management and how this disease fits in with large urology group practices.

First, I'd like to ask Gary Kirsh a straightforward question. Gary, in the past 2 years, how have LUGPA practices changed in their offerings and patient care toward advanced prostate cancer?

Gary Kirsh: Well, Dave, thank you for the opportunity to speak with you. Over the past 2 years there has been steady growth and progress in having large urology groups adopt and embrace the care of the advanced prostate cancer patients. I would not say that this has been easy. It takes time to educate and change practice patterns. But, since sipuleucel-T was approved in 2010, the past several years have been real momentum changers, with a number of groups adopting advanced prostate cancer clinics and getting involved in the whole spectrum of care.

David Albala: Let me ask you a further question in this area. We've seen large urology groups develop this area of advanced prostate care in some ways much more than academic practices have developed it. In other words, in the academic setting, many of these advanced prostate cancer patients are referred to the oncologist, away from the urologist. Why have the large urology groups been so successful in keeping these types of patients in their practices?

Gary Kirsh: There are several reasons. The large groups recognize—or urologists in general should recognize—that these patients are principally the patients of the urology practice. The patients have long-standing relationships with their urologists. Urologists are quite capable of delivering the therapeutics that are available today, with the exception of chemotherapy, which is an important agent.

There is a situation in which the urologist recognizes that this is a urologic disease; therefore, increasingly there is patient benefit and practice benefit to keeping these patients within the urology practice. The large groups in particular are well suited to do that, as opposed to smaller urology groups, because they have the scale to designate subspecialty positions to learn clinically about this. They have the administrative mechanisms to look for patients who have castrate-resistant prostate cancer who need to be referred to specialists. Another aspect is the academics—they are good people but they are mired in the politics of their institutions, and they get dissension from the oncology department if they try to encroach on oncology practice. Within the setting of large urology groups, we don't have these problems. We have independent groups and can control our patients; it is not an issue for us. I think that is why it has developed so well in the large urology group setting.

I also think that we are doing a very good job. Really without throwing any stones or casting any aspersions on our medical colleagues, I think we are doing a better job for the patient than if all the patients go to oncology treatment. Patients don't want to go to oncology departments if they don't have to. They see it as a defeat clinically for them. Frankly, oncologists are very busy with a wide array of oncologic conditions, and urologists are capable of being focused and knowledgeable regarding advanced prostate cancer and are doing a good job for the patient as well.

David Albala: Now let's turn to Dr. Shore. Neal, in the next 2 years, how do you think LUGPA practices will improve their advanced prostate cancer offerings in patient care?

Neal Shore: Well, I think there have been tremendous strides in LUGPA practices since 2011. At LUGPA, one of our very first continuing medical education (CME) annual programs was in educating our membership on the importance of the burgeoning approved advances for castration-resistant prostate cancer (CRPC) patients. It has been very heartening to me to witness the rapid adoption of LUGPA practices in establishing advanced prostate cancer clinics. Since that initial CME program in 2011, we have had several additional advanced prostate cancer focus courses for our membership.

During this time, there continued to be additional approved agents for advanced prostate cancer survival and improvements in quality of life. Furthermore, there will continue to be ongoing advances in multiple different types of therapeutics. The most recent therapeutic that was approved by the US Food and Drug Administration was targeted alpha therapy known as radium Ra 223 dichloride.

Many of our LUGPA practices have had a very healthy and integrative relationship with not only their medical oncology colleagues, but also their radiation oncology colleagues and their nuclear medicine radiation oncology colleagues. It is wonderful for patient outcomes that therapies can be offered to LUGPA member practices that are dedicated to advanced prostate cancer optimization.

David Albala: Gary, in your opinion, what have been the largest clinical advances in advanced prostate cancer care in the past 2 years?

Gary Kirsh: In the past 2 years I would say, without knowing the exact timing, the emergence of radium Ra 223 dichloride has been important. Although the oral agents have been available for several years, one of the things that has become important to practices has been the adoption of oral dispensing operations—pharmacy

operations within the large practices. This allows the practice to have better control of patient care from beginning to end. That is increasingly important as we move toward value-based compensation. Some of the advances have been not only clinical (with the emergence of oral agents and radium Ra 223 dichloride), but also on the business side of practice, with the development of pharmacies within these practices, which was not seen to any great extent until recently.

David Albala: Neal, what are the key clinical questions in advanced prostate cancer care that we may need to develop in the next 2 years? In other words, if I had a crystal ball, what new developments are coming that will help us treat patients with advanced prostate cancer?

Neal Shore: That is a wonderful question. We are always trying to meet the unmet need of curing the disease in all patients who are diagnosed. Historically we have tended to think about advanced prostate cancer within the group of patients who developed CRPC, formerly referred to as hormone-refractory or androgen-insensitive prostate cancer. We now know that CRPC patients respond not only to novel oral hormonal therapies that target the androgen access, but they can also respond to radiopharmaceuticals such as radium Ra 223 dichloride, which is life-prolonging therapy, as compared with the historic radiopharmaceuticals that were given only for palliation. These developments, in addition to the advances made with immunotherapeutic agents such as sipuleucel-T, make treatment care for these patients very promising.

And we can't forget that taxanebased therapy plays an important role for these patients as well. We're also on the cusp of developing other types of oral therapies regarding DNA repair mechanism defects known as the poly(ADP-ribose) polymerase inhibitors. For me, and I think for LUGPA practices and for all of urology practices moving forward, the definition of advanced prostate cancer starts with any patient who fails primary interventional therapy. I believe patients should be included as advanced prostate cancer patients as soon as biochemical or prostate-specific antigen relapse is noted, when patients are androgen sensitive. This also includes the increasing percentage of patients who present with newly metastatic androgensensitive disease.

One of the results of this is realizing the complexity for deciding upon not only the traditional trigger to initiate androgen deprivation therapy—about which we've learned so much over the years—but that there really are associated risks and benefits that have to be assessed. I'm excited about the potential for non–androgen-deprivation therapies for our patients in biochemical relapse, in addition to curing our CRPC patients.

I would be remiss if I didn't speak to the explosion of diagnostic modalities that will better inform us from a radiographic standpoint regarding various positron emission tomography (PET) tracers that will establish in the newly diagnosed patient with or without micrometastatic disease. Certain types of PET tracers, along with the existing genomic assays, will help us better evaluate whether a patient is an ideal candidate for active or interventional strategies.

The bottom line for LUGPA practices is recognizing that advanced prostate cancer patients who have failed interventional therapy should be sent to true dedicated specialists

within the LUGPA practice. This is a challenge for many of our practices because, historically, so many of our colleagues want to take care of their prostate cancer patients from diagnosis to death. This is no longer easily accomplished given the complexity of diagnostic, therapeutic, and management skills required to do what is in the best interest of these patients.

David Albala: Gary, in 2 years what do you think a large urology group practice will look like as it relates to advanced prostate cancer? Is there going to be subspecialization, service line integration, clinical trial participation, nurse navigation, and technology for population health management and patient identification? Is there going to be a care team approach with clinical, business, operational, and radiation oncology teamwork? Can you give us some insight as to how you think this will emerge as we move forward?

Gary Kirsh: I hope it's exactly what you laid out and it's all of the above. We need a better infrastructure for many of our practices from the electronic medical record standpoint. We have to be able to do a better job of identifying patients; we need better ability to practice protocolbased medicine within groups and have that monitored electronically. That is very difficult to achieve. I see these capabilities emerging.

I do see more therapeutics on the horizon. In 1 to 2 years, we will probably have M0 approval and several years after that we'll have other approvals in the oral therapy area. There could be additional immunotherapies approved in the next several years. And there will be a push—I don't know if it will be successful or not—for some practices that are serious about this and more robust in their capability to begin doing chemotherapy. I think

an evolution will take place on the clinical side.

From a cultural side, it is important that groups advance with regard to their business and clinical and cultural integration. We still see obstacles all over the country to developing robust subspecialized prostate cancer centers due to the reluctance of doctors to share their patients with each other. This has to stop because the future of medicine requires more clinical integration among partners. That is an obstacle that we will see start to fall away in the next few years as well.

David Albala: Let me ask Neal the same question. Looking forward into the future, how do you think a LUGPA group will look as it relates to prostate cancer treatment? All of these approaches have been put forward as ways that practices can integrate and develop these service lines as they relate to advanced prostate cancer treatment. Do you think all of these can be integrated—the subspecialization, service-line integration? Obviously, you have had tremendous experience with clinical trials and nurse navigations. What is your recommendation for groups? How should they integrate these component parts?

Neal Shore: Regarding this question, and the multitude of service lines and key stakeholders within a multidisciplinary team that make for the best outcomes for patients and the best value to the health-care system, it will require all of the aforementioned strategies. The key to gaining this success is to recognize that it is not a one-size-fits-all approach.

We are all aware of the heterogeneity of prostate cancer, and, in a correlative fashion, there is tremendous heterogeneity in how different LUGPA practices can effectively develop and maintain an advanced

prostate cancer clinic of excellence. There are different strategies for nurse navigation and data mining. There are different strategies for collaboration and subspecialization within a practice. As long as the patient is getting the best care and it is being done in a fashion that creates value, or Michael Porter's definition of outcomes divided by cost, which should parallel the goals of the Triple Aim as well as the Medicare Access and CHIP Reauthorization Act (MACRA), then we are doing the best we can.

I would add that we want to make sure that when we develop an advanced prostate cancer clinic, we do it in a way that promotes the healthy enjoyment of that career for the urologist involved, which is, interestingly, never discussed within the Triple Aim goals or within the MACRA legislation. We often hear about physician burnout and frustration. I think that one of the salient aspects for all of genitourinary oncology has been these incredible advances. Thanks to our preclinical expertise and our industry and government and academic research leaders, it gives clinicians who are very busy in the trenches taking care of these advanced cancer patients an opportunity to be fulfilled and really do yeoman's work within the community.

We want to keep these patients from dying of their disease. We want to keep them from entering into the complications of their treatment and maintain a high quality of life. I think this is all within the realm of an advanced prostate cancer clinic and integrated independent LUGPA practices. I would add that we are also going to see the same notion of advanced cancer care directed toward advanced bladder and kidney cancer care.

David Albala: What would you say to a group that is reluctant to invest

in an infrastructure service line for advanced prostate cancer?

Gary Kirsh: I would tell them that there is not much of an investment. I would tell them that it is actually a profit center, and we have proven that. This is a scenario in which what is great for the patient is also great for the practice. Is the technology absolutely appropriate for the care of our patients? In the situation of advanced prostate cancer, to fail to deliver that care to a patient base is bad medicine. To deliver the care is good medicine, and to deliver the care is profitable and good for the practice. The alignment of incentives to get this done is extremely high, both economically and with regard to what is good for the patient.

The barrier has been the cultural integration. The ability of these groups to integrate clinically and put systems from a business perspective together to identify patients and to share patients has been the barrier. Advanced prostate cancer is a good test case as to whether a practice can integrate around a relatively limited condition; if they can't integrate around a relatively limited condition, they're not going to be able to integrate around a whole host of conditions if they're going to integrate in the future.

Neal Shore: If there is a group—regardless of size—that is not interested in the pathophysiology of advanced cancer care, they should ensure that they are sending these patients to the clinician care team that has the interest. If there's a urology practice that is focused on nononcolytic care or only on primary intervention, and they're doing those things well and they are happy and satisfied, then that is fine for their decision making. It seems reasonable if they are

happy with that clinical and business paradigm, as long as they're making sure that their advanced genitourinary oncology patients, specifically their prostate cancer patients within this discussion, are getting the approved and appropriate care.

Having said that, prostate cancer care is really a core clinical model for the successful mainstay of an integrated urology practice. For any group that has a significant size, I find it very hard to understand why that decision would be made, but there are always exceptions. One exception could be a wonderful collaborative relationship with their medical oncology, radiation oncology, and nuclear medicine teams, and radiation and/or primary care colleagues. It has been my experience that that is usually not the case, and certainly not the case within the US communitybased healthcare systems, which is why I think advanced prostate cancer, advanced bladder cancer, and renal cancer treatment will eventually find maximum efficacy and value outcomes within large urology group practices.

The notion of what is large or small has always been somewhat of a difficult question. I don't think there is a binary number that describes large versus small in an acceptable way. We know there can be a 3- to 5-person group that is so hardworking and so well integrated that they completely surpass a 20- to 30-person group. Much of the definition of large depends upon the integral components of the work-through product, the culture of collaboration, and integration within any of these practices.

I often hear our colleagues proudly talk about the number of clinicians in their group, but I also recognize that a group of 3 to 10 can provide as good, if not

better, care than a group of 75 to 100. Size alone is not always a perfect correlation with outcomes. Size, within healthcare systems, primarily speaks to volume relationships. In the ideal world, a high-volume large group that has identified its pathways of integration and specialization should be the goal for health care within the country.

David Albala: Thank you. One last question: how do you think tomorrow's urologists are going to be prepared for the complexity of care in this advanced prostate cancer space?

Gary Kirsh: Do you mean in terms of training?

David Albala: Yes. How do you think that urologists are going to be interested and prepared? What should the urologist do who has little training in advanced prostate cancer? How can he or she become prepared to take care of these complex patients going forward?

Gary Kirsh: That's an excellent question, and it's a big problem. We are now seeing doctors who have taken this on as early adaptors and who have become relatively facile at it. But, as we try to expand this to more groups, and as those doctors turn over within a group, we see difficulty with the training and the transition with respect to this disease state. One of the problems I should mention

is in our academic programs, and I hope that this comes out in this interview. I have had discussions with many department chairs who tell me that urology residents are not being trained on how to treat patients with advanced prostate cancer. This is a big disservice to our profession.

The residency programs cannot be focused solely on robotic surgery. I have hired residents for my practice who have no idea and no interest in taking care of these patients, so we can't rely on the residents. We have to train our own doctors, which is difficult. There isn't a series of training courses available for residents. The training courses have been limited to the basics; what we see now is the need to take the doctors who have the basics and give them additional training.

We are working on that. There have been some courses through the American Urological Association (AUA) and LUGPA. LUGPA did a Prostate Cancer Academy in association with MedReviews, LLC (New York, NY) in September 2016. There are training platforms, but it's difficult. These are busy, practicing doctors. They have to have the will and commitment to go forward with this training and we are getting no support from the training programs.

Neal Shore: Staying on top of the ever-developing sources of new trials, data, publications, and presentations is a challenging issue

for many of our advanced prostate cancer clinics. At LUGPA in 2017, and as the president of LUGPA, one of my initiatives is to start a password-protected ongoing quarterly Web-conferencing for our members who are dedicated to advanced prostate cancer care.

My goal is not to have a recitation of the well-known guidelines, whether they be the AUA's or those of the National Comprehensive Cancer Network, and not to go through basic definitions of advanced prostate cancer care, or the journey of the advanced prostate cancer patient. Rather, the goal of this ongoing live Web conference is to constantly review the latest presentations, publications, and trial literature so that our incredibly busy colleagues can stay up to date when they are not able to attend these conferences and/or read all of the Web-based or hard copy literature. I hope that this will create an added value for our LUGPA practice members so that they will be able to listen to the primary investigators or principal authors of the most cutting-edge presentations and newest literature.

David Albala: I'd like to thank Dr. Kirsh and Dr. Shore for sharing their insights. This was a wonderful conversation. I look forward to seeing what large urology groups will look like with regard to advanced prostate cancer treatment in the next 2 to 5 years. Thank you very much.

This transcript has been edited for style and clarity.