Bladder Cancer and COVID-19 | West Coast Regional Update for Patients and Families.

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BCAN | Stephanie Chisolm:

I'd like to welcome everybody to bladder cancer and COVID-19 West Coast Regional Update for patients and their families. My name is Stephanie Chisolm and I'm the director of education and research at BCAN. We're really delighted to have a number of doctors here joining us from the West Coast. We are really happy to have medical oncologist, Dr. Sandy Srinivas from Stanford University in Palo Alto. Welcome Sandy. It's nice to have you here. And Dr. Alex Koo from Skyline Urology in Los Angeles talking to us. We may have a few other guests in just a little while. We'll see if they're able to get in with the technology or not.

BCAN | Stephanie Chisolm:

I'd like to open it up with one quick question right off the top. We know that everyone is practicing social distancing, and the concept of medical distancing for bladder cancer patients, is something we're only now beginning to really experience. Where patients are being told that they should postpone their treatments or postpone their surveillance. Dr. Koo, what are you seeing in your office and in the hospital where you practice, about changes in protocol for normal bladder cancer patient treatment or surveillance? What is being done to protect patients and also to the staff? What are you seeing there?

Dr. Koo:

Thank you, Stephanie. So first of all, with the advent of this pandemic and the virus, there's been pretty much a mandate starting from the government, Department of Health, on down to hospitals and surgery centers. So that in the hospital setting we only do surgeries on what's deemed to be urgent or emergent cases. All the other cases that are called elective are being delayed.

Dr. Koo:

In our office we actually continue to see patients, certainly patients who have urgent or emergent needs. I like to think of treating the patient, as opposed to a disease. So what's urgent and what's emergent to us is, there's a huge variation in different physician practices. And so to us, with the urgent and the emergent patients, we take into account of what the patient's feelings are. If the patient deems a situation to be urgent, then we see them. It's really the patient's choice. It may be due to high degree of health anxiety, or information seeking, but that's why we're here. We're really here to meet those needs. In the office as you know we use masks; the staff is wiping down the waiting room several times a day and wipe down the room and each of the patient treatment rooms in between patients. So we're taking all precautions in trying to be safe.

BCAN | Stephanie Chisolm:

Thank you. Dr. Srinivas, you're in a large university practice as a medical oncologist, what are you seeing as far as, are things changing for you in how you see patients? And any protocols changing? Any things that patients should expect when they show up at the hospital?

Dr. Srinivas:

Well, thank you Stephanie. California went into a sheltering place around mid-March. I think it was around March 19. Almost every week we have adapted to different changes. The first thing that happened immediately was all of our patients, we quickly transformed them into video visits. These are cancer patients, their care and their cancer continues. So we have to find ways to provide them that best care that we could deliver.

Dr. Srinivas:

So almost in the first week we had to come up with the list, figure out who are the patients for whom we could do video visits. I was amazed by how quickly our institution reacted to giving us all computers that had ability to do video visits. Because our first intent was to keep patients safe, our staff safe, and also our providers to be healthy in order to provide the care.

Dr. Srinivas:

So I would say 75% of all of our visits within the first week quickly got converted to video visits. Each week, again as I said, things keep changing. The second week around we had to come around who should be wearing a mask. So right now our outpatient protocols are that patients are called two days prior to their visit. First to have to screen whether they have any symptoms, and only those without symptoms come directly to the cancer center.

Dr. Srinivas:

When they come into the cancer center, all of them have their temperature taken. They are all given a mask to wear. Those who have symptoms are taken to a separate clinic across from where the cancer center is, where they would then get their COVID testing done. So all of these changes have been so dramatic and typically change week by week. We are now looking into protocols about how our cancer patients are? Should they be tested? Should every asymptomatic patient be tested? We are looking into all cancer patients getting elective chemotherapy, have their testing done. So this is pretty remarkable. And I would say probably the thing that really amazes me is the way information is being delivered. We had all of our medical grand rounds converted to just information on the virus, about the virus, what the testing should be done, how the testing is changing.

Dr. Srinivas:

We are having different tests being done as well as what are the current clinical trials that are available to us. All of this being done via grand rounds, via town hall meetings. So the information that's being provided to us, is at an amazing speed as well.

BCAN | Stephanie Chisolm:

It really is a work in progress. Everyone is learning on the fly. I think that this is something that we'll continue to see as we move through this virus, as it becomes more and more prevalent. I don't know that what you're seeing in the California area is as prevalent as say, what we're doing on the East Coast. In the New York area was very different from what we did in the Southeast when we did this program last week.

BCAN | Stephanie Chisolm:

So in terms of looking at predictions, you all are ramping up obviously to prepare as necessary to make changes. We just talked to Dr. Srinivas about how things are changing on a week to week basis. So from that perspective then, as far as what is really kind of considered in this central thing for you to come in, are you changing the way that you're seeing patients for chemotherapy at all? Or for immunotherapy? Are you obviously starting patients off when they need this therapy? But are you changing the protocols at all for patients who've already been on this therapy?

Dr. Srinivas:

These are all individualized. We don't have one size fits all, because every patient's need is very different. I think about patients with bladder cancer as those who have localized disease, those who have metastatic disease, and those who have more advanced disease who are on subsequent lines of therapy.

Dr. Srinivas:

So clearly the patient with localized disease, we know that has a potential for cure and beyond Corona [virus], we need to continue to have good outcomes for patients with bladder cancer. So one of the earlier approaches we took as a multidisciplinary team, and along with consultation with our urologist as well as our radiation oncologist, is who do we give chemotherapy to so that we can briefly postpone and perhaps cystectomy? Which is definitely a much bigger procedure.

Dr. Srinivas:

Patients may have risks for readmission exposure to the hospital. So there were a lot of those things that were taken into consideration. So for the localized patient, we continue to give them chemotherapy, but use a chemotherapy that requires less visits to the hospital, maybe more biweekly as opposed to a weekly regimen.

Dr. Srinivas:

And for those patients whom we were committed to giving chemotherapy, we definitely wanted to give them growth factor support. We wanted to give them anything to keep them safe so that we could deliver this chemotherapy without them getting a risk of developing neutropenia and therefore requiring hospitalization. We even considered giving prophylactic antibiotics to decrease the risk of them getting readmitted.

Dr. Srinivas:

For the immunotherapy patients, while immunotherapy is definitely less myelosuppressive than chemotherapy, one of the concerns is that they do develop new mediated side effects. They require prednisone and there's always a concern about giving them more prednisone and making them somewhat more immuno-suppressed.

Dr. Srinivas:

There is a lot of juggling and I'm not sure we can come up with one size fits all. Every patient is being considered now based on their age, based on their comorbidities, based on their clinical stage as to what can be done and whether it can be safely postponed or not.

BCAN | Stephanie Chisolm:

I'd like to welcome Dr. Sia Daneshmand. He is a urologist at Keck School of Medicine at USC in Los Angeles. Welcome Dr. Daneshmand. It's nice to have you join us.

BCAN | Stephanie Chisolm:

I'd asked Dr. Koo to talk a little bit about some changes in protocol that have been going on with medical distancing within the community practice, and Dr. Srinivas was talking about medical oncology. So from your perspective as a urologist at USC, you're seeing a lot of patients in a large academic situation, are there changes that you are implementing in standard protocol for bladder cancer patients that you might be able to talk a little bit about?

Dr. Daneshmand:

There are certainly difficult times now we're trying to still optimize treatment while minimizing delays. And also trying to deliver the best quality care. I think we split it into clinic versus open room visit. So in the clinic we're continuing to do the surveillance cystoscopy that are required for high risk patients. The ones that are in what we call the AUA high risk category patients with high grade non muscle invasive bladder tumors that are on the three month schedule of cystoscopy. So those who are continuing as is, because the volume of the clinic has substantially decreased, those are essentially one of very few patients who are actually coming in, because we can't do telehealth for those patients telemedicine visits. So those we continue to see [in person].

Dr. Daneshmand:

We also have urged all patients to continue with their BCG therapy, if it's induction BCG or induction chemotherapy. That's the first of six weekly treatments of any kind of treatment that we've prescribed for them. There's no delay there. However, if you're beyond two years and you're slightly lower risk and or you're on maintenance therapy, those patients certainly can wait an additional two months to come in for their cystoscopy, because it most likely will not make much of a difference in their overall outcomes.

Dr. Daneshmand:

So again, to summarize, surveillance cystoscopy and intravesical therapy for high risk patients, we're continuing. I'm trying to do more in the clinic as well if there's a suspicious lesion in the bladder that normally we might take to the operating room. We're preparing ourselves to do biopsies in the clinic itself to avoid that additional visit to the operating room.

Dr. Daneshmand:

As far as patients who are higher risk and need to go to the operating room for transurethral resection of bladder tumors, [those with] existing bladder tumors, again, it's risk stratified. If you've had a small tumor that's recurrent from a low grade cancer then certainly we're waiting additional two, three, even months to do the resection. I don't think there is much risk of progression again if you're low grade.

Dr. Daneshmand:

A high-grade tumor is different. If it's a larger tumor, we're concerned that this changes our management and certainly we're taking those patients to the operating room right now as well. Cystectomies are also considered sort of high-risk situations. Where if a patient does require radical

cystectomy, removal of their bladder whether it's after neoadjuvant chemotherapy, there's really a window of opportunity time that's about eight to 10 weeks, or whether it's someone who were taking to the operating room because they have a high grade non-muscle invasive bladder cancer.

Dr. Daneshmand:

Those should be done in a timely manner as well, and typically we get very uncomfortable waiting more than three months from either chemotherapy or last time uses of muscle invasive bladder cancer. So again, risk stratified and we're trying to maintain care as best as possible.

BCAN | Stephanie Chisolm:

Dr. Koo, Dr. Srinivas, do you have anything else to add?

Dr. Srinivas:

Well, I agree with what Sia said. I think we are doing something that is similar, because we did the shelter in place. I think we've been a little fortunate that overall, we have not seen as many as we had anticipated. So I think the hospital is very comfortable with the processes that have been in place this far.

Dr. Srinivas:

Like I said in the beginning, Stephanie, every week things change since we have done well we are beginning to talk about is it time to open up the operating room to other cases? So we are very hopeful that we delayed patients safely, for the first three to four weeks. Moving forward we may have an opportunity to get back to where we need to for their cancer care.

BCAN | Stephanie Chisolm:

Can you comment on when is it okay [to delay treatment]? I think that's a big concern that we hear from a lot of patients. They're worried, "My doctor's telling me I don't need to come in right away, but this is really worrying me. Should I go find another doctor? That is what they're asking BCAN. And so what are some of the general things that you could safely, comfortably say, "These are usually an okay [to wait] situation?"

BCAN | Stephanie Chisolm:

Dr. Koo. What are some of the okay situations for surveillance or for treatment where you feel like, "I don't feel this person is at greater risk, because if we delay a few weeks till things quiet down health wise, they'll be okay." What are your thoughts?

Dr. Koo:

Our approach is that it always should be, the patients should be given the maximum amount of information that he or she could assimilate. Then the decision could be made in a shared decision-making process. So there's nothing that comes down from above. So that being said, there are some rules, Dr. Daneshmand has mentioned several of them. It really is a risk benefit issue.

Dr. Koo:

What is the risk to that specific patient in terms of COVID virus exposure? Taking them to the hospital, placing them in potentially higher risk situations, versus the risk of their disease. And as Dr. Daneshmand mentioned for patients who are several years out from their initial bladder cancer [diagnosis] and they're just here for their annual follow-up. Delaying that by two, three months is probably not much of a risk as far as the disease of bladder cancer is concerned. And so those are probably clear cases where you could safely delay. At the other spectrum there are people with large newly diagnosed aggressive cancer who may even be symptomatic then they clearly are emergent, urgent cases, and then there are the people who are kind of in between.

Dr. Koo:

And I think it's important that through telehealth that the patient can schedule a session initially just to make sure that the patient is fully apprised of the risk of the disease and the exposure versus the risk of the virus. I think it needs to be done on an individual basis with full information.

BCAN | Stephanie Chisolm:

Dr. Daneshmand, could you have anything else to add?

Dr. Daneshmand:

I agree. Again, sort of we're risk stratifying. The other thing is, patients should be aware that of course we're taking every precaution when they do come in. They're wearing masks, we're wearing masks and we're trying to really make the experiences as sterile as we possibly can make it. We need again, very little interaction with other patients around. So they come in, get their assistance and they're out as soon as possible, with minimal interaction with staff. We're trying to make that as safe as possible as well.

Dr. Srinivas:

Where you're doing just surveillance with scans, that's absolutely safe to wait and delay coming in just to get the scans done. For patients who are getting immunotherapy, we know from the past and from multiple trials that have been done, that patients who stopped immunotherapy because they had, for instance, side effects, we continue to see them derive clinical benefit.

Dr. Srinivas:

I would say for patients who want to delay one or two doses of immunotherapy while they are responding, that's probably very safe to do and I would feel very comfortable postponing that treatment. Somebody who's symptomatic from chemotherapy, that's a tough one to stop, because bladder cancer is a more aggressive cancer compared to let's say, prostate cancer, whether it's okay to wait on some treatments.

Dr. Srinivas:

So patients who are symptomatic unfortunately that is hard to postpone, and that's why we bring patients in, but try to deliver that chemotherapy in the safest possible way with either growth factors or with other ways to deliver the chemotherapy in a safer way.

BCAN | Stephanie Chisolm:

I think that's really important information to have, especially in the sense that the immunotherapy does have a little longer sort of in your body life, that it does offer some protection for a little bit longer. That's something that a lot of people don't realize.

BCAN | Stephanie Chisolm:

So in your mind, what constitutes an urgent need for care? I know that patients themselves are also afraid to come into the doctor's office afraid to go to the hospital because of the increased risk. I know our community is very much concerned that just having that bladder cancer diagnosis puts them at additional risk, and then knowing about the risks that they become immunocompromised with some of the treatments that they might have. What are some urgent, "You need to come in. You need to let us know what's going on," that we should be telling our community about?

Dr. Daneshmand:

I can start with that, because I've had certain situations where patients have called and asked if they can wait. And I've said, "No, I think you're high risk." So patient who needs to really come in is that first assessment following intravesical therapy. Someone who has a high-grade Ta tumor has a non-muscle invasive high-grade Ta or T1 invasive but not muscle invasive, and just underwent a six-week course of BCG or other intravesical therapy. That patient really needs to come in for a three-month assessment, because it's critical we know whether the patient responded to BCG or not. If they haven't responded we need to move on to intravesical therapy, but delaying surveillance for instance in that setting is not advisable.

Dr. Daneshmand:

The other question that comes up is, "I finished my chemotherapy a month ago, can I just wait another two months? My BCG scan says everything is okay." So we and others have published studies that show an eight week delay following neo-adjuvant chemotherapy is probably fine, but more than that is not. There are stage migration [and] stage progression that we see after eight weeks, certainly after 10 weeks, and the more aggressive the tumor, the higher that risk is.

Dr. Daneshmand:

So those are urgent ones, also bleeding. New onset bleeding in a patient who had been disease free for some time that's not something we want to hold off, because it can move fairly quickly to higher risk disease.

BCAN | Stephanie Chisolm:

Dr. Koo, are you seeing anything different from when you should come into your office? Or when you should meet your patients at the hospital? Is there any difference that you're seeing what is urgent care from that perspective at this point for you?

Dr. Koo:

Dr. Daneshmand has had some really good points and I think the additional item will probably just be really taking into account patient's feelings or patients own perception of the urgency. And there could be anxiety, there could be a lot of fear of the unknown. And so a conversation with knowledge can often help with that. And there are other ways that we could reduce the risk.

Dr. Koo:

A number of my patients who were anxious about going to the hospital we were able to channel them to community-based radiology offices for MRI, CT scans and bone scans or even PET scans occasionally. They feel much more comfortable in those settings. So there are different ways to work around that. A lot of it is for the intermediate risk group of patients and the risk is constantly changing with the timing.

Dr. Koo:

A month ago when we first went into the lockdown phase, I think it's probably clear to most of us that it was not going to be over in two weeks. We're looking at more of a two month period. So if delaying treatment diagnosis by two months which can be of significant risk and those people are really deemed urgent.

Dr. Koo:

And now I think we're looking at perhaps, you never know, maybe in a month we could start to relax at least in a gradual fashion the distancing rules. So delaying people at this point by a month is certainly a lot of less of a concern from the cancer treatment standpoint than a month ago.

Dr. Daneshmand:

Now I should've mentioned one of the thing here that if patients are concerned that... And Alex brings up a great point about patient concern versus what we know about their risk status. There are patients who really don't want to wait. They're asking us to come in, and we're telling them, "No, it's okay to wait."

Dr. Daneshmand:

Well, one solution potentially could be the use of some urinary biomarkers that at least give us some information. What do I mean by that? We're working with Pacific Edge. It's a company that has a urinary marker called a CX Bladder, and they've developed a home kit so that we can send this kit home.

Dr. Daneshmand:

Basically the patients will give us a urine sample, we fill in the information, the urine gets sent to the lab and we get the results back and then we can have a telemedicine visit with the patient and tell them that that test came back negative, and the negative predictive value of the test is extremely high.

Dr. Daneshmand:

So it has about a 98.5% negative predictive value. That means that if the test is negative, there's a 98% chance you don't have bladder cancer. So we're working with them, and several groups including UCSF to see is that a feasible sort of thing. I know that in New Zealand they had done that very successfully.

BCAN | Stephanie Chisolm:

I'm sure that that would go a long way to make patients feel a little bit less stressed about the great unknown of not knowing if their cancer might've come back, if in fact you've got such a high predictability and an accuracy to say now we're pretty confident that you don't have anything back in your body right now. So I think this is a really interesting opportunity to be able to do this remotely. And then they just mail it in. is that what you're saying?

Dr. Daneshmand:

Yes, exactly. I mean it's not every patient, but the ones who we sort of say that this is a perfect sort of test you're a year and a half, you're not exactly high risk, you're not low risk, you're not in the immediate risk category and the patient wants to do something. This is a great segue to hold on, until the next visit and I think that's a really a good way.

Dr. Daneshmand:

And of course we're turning this in also into a research question as to is this feasible going forward? Can we instead of having patients drive two hours to every other visit for instance, and do this as a feasibility sort of test?

BCAN | Stephanie Chisolm:

I suspect that when this is all over and everybody has a deep breath, they'll be able to write up some really game changing articles in the future. Dr Srinivas, what are you thinking as far as clearly dealing with chemotherapy and immunotherapy? Both have very adverse events from a medical oncology perspective with bladder cancer patients. When is this urgent come in for care? Or when is this, "Well, we'll do telemedicine?" What do you think? What are some of the things you can share?

Dr. Srinivas:

Well I think our first goal here is to try to avoid emergency room visits. That's always been our goal, but I think now with the viruses even more important that we try to get our patients to either come to the clinic, or do telemedicine and try to avoid ERs or getting admitted into the hospital.

Dr. Srinivas:

So for patients who are on chemotherapy, one of our concerns is as we are screening and patients taking outside calls, we want to make sure that the patient who's on chemotherapy who may be having a fever with neutropenia doesn't get missed. So I think any patient who has a fever, who's been on chemotherapy requires an urgent evaluation.

Dr. Srinivas:

Our goal would be, the good news is that we are all working, but we are just working in a different way. All of our staff are in the office. Those who are taking frontline phone calls are all alerted about the patients and what to expect. So I would say any patient with fever requires an urgent assessment, whether that is via telemedicine, where they're coming into our clinic to get their blood work done, maybe get a chest X Ray, maybe get that, usually valuation is something that needs to happen.

Dr. Srinivas:

For all patients on immunotherapy, we have given them the spectrum of things that they should be concerned about. The usual ones of having increased shortness of breath, having increased diarrhea, all of this requires a phone call evaluation. And I think now that we have video visits and telemedicine, I think patients should take advantage of that and be able to access the clinic so that the clinic can then judge what the severity of that illness is, so that they can then make the assessment as to where would be the safest place for the patient to be evaluated.

BCAN | Stephanie Chisolm:

Obviously if say this urine biomarker test is something that's going to be tracked to see if it's effective, do we see that there are other things that can be done outside of the doctor's office? Is there anything else that's moving in the direction of being home care that you can see?

Dr. Srinivas:

Well, I'll tell you that home care is definitely something that's going to happen beyond this media period that we are in. Home care monitoring for patients with just blood tests who are not on treatment, I think it's going to be something that's going to continue. Telemedicine and video visits are definitely going to continue beyond just the space. We've been thinking about this for a while, but for a lot of reasons haven't been able to execute home delivery of chemotherapy, home delivery of IV infusions. There are a lot of supportive care treatments that probably can be done outside of the infusion centers. These are all some things that I think we'd start thinking more creatively as this opportunity has come by, which allows us to identify who are the patients and for where the care needs to happen.

Dr. Daneshmand:

I think those are great points and I think we should take the opportunity to see whether we can actually even deliver intravesical therapy at home. These are very safe sort of delivery if you are an oncology nurse who's well versed in handling of the medicines? I know that in Iran for instance they are doing BCG at home.

Dr. Daneshmand:

Health nurses are coming in and actually doing it so that the patient doesn't even have to come into the hospital, especially when they had the surge there and that at hospitals was full of COVID patients. So perhaps for the patients who have difficulties coming in, this is something we should be looking at.

BCAN | Stephanie Chisolm:

So anything else that you can think of before we open it up to questions from the audience? How might the things that we're learning about COVID-19 specifically in the bladder cancer population change how things are going to be done in the next few weeks or the next few months?

Dr. Srinivas:

Like you said in the beginning, we are learning as we go along, but this is also an opportunity for us to understand how outcomes are going to be in cancer patients. So to that end, there are international registries that have already started looking at patients with cancers and including patients with bladder cancer who have tested positive and what their outcomes are.

Dr. Srinivas:

There are international registries, and I think even ASCO is collecting information on patients with various cancers to test positive. So these are all opportunities for us to understand more and understand what the outcomes, including clinical trial opportunities that might arise from this.

Dr. Koo:

This is actually more of a call out for all the patients and family. So one of the things that we've learned through this crisis and the silver lining is it kind of pushed telemedicine into the forefront, and physicians have now acquired the capability delivering health care to telemedicine. But it is only possible because during this time that the payers from Medicare and all insurance companies have agreed to reimburse for telemedicine care.

Dr. Koo:

Is this all going to go away? If the reimbursement goes away after the crisis is over, then telemedicine will go right back to where it was. And my other hat, I'm actually a health policy expert in urology and through years of lobbying in Washington DC we know that the Congress loves hearing from patients. They really don't like hearing from doctors. They view physicians with a lot of suspicion, but whenever there are patient support group that contact the Congress, their message is actually always very well received. And I think telemedicine is going forward. It's going to be a key part of care delivery and we need support from the community.

BCAN | Stephanie Chisolm:

Everybody has been talking about this and all of these programs, telemedicine is key to keeping patients connected and keeping them out of harm's way in terms of reducing their risk of exposure. I feel like BCAN would definitely be willing to help out in whatever capacity by engaging the community should things change and it reverts back that telemedicine is not an option anymore.

I think that that would certainly be something that as an organization we can certainly get behind because this is very much relating to care for the patients and helping to control the cost and the time and everything else. If you can make a telephone visit with your doctor and not have to drive two hours, I think it would be a huge improvement.

BCAN | Stephanie Chisolm:

I'd like to try to do is open it up to questions from our participants. Do you have any sense of how current guidelines affect physicians review of clinical trials options?

BCAN | Stephanie Chisolm:

I know that many of you were engaged in clinical trials in some capacity. What are you seeing with those clinical trials? Are they ongoing? Are they stopping right now? I know that there have not been as many clinical trials that are opening up right this minute, because if you're not a COVID-19 clinical trial, you're not necessarily getting the priority. But what are your thoughts on what's going on with clinical trials right now?

Dr. Daneshmand:

So I can tell you because I just put somebody on a clinical process just right now. So the guidance from the NCI, National Cancer Institute is that if it's a therapeutic trial, meaning there's medication involved, that we're giving a patient with respect to minimizing the other staff like try to get the patient on the trial, and get them to medicine they need. The prime example of that is SWOG 1602 trial intravesical BCG the American TICE strain versus the Tokyo Japanese strain.

Dr. Daneshmand:

That is a therapeutic trial, and because we have the BCG shortage right now that is a very, very important trial. So we're continuing enrolling in that trial. There are a number of other options available for patients who have not responded to BCG. And again if those trials are open and your institution allows it, there's going to be some variability among institutions, but the overall message here is that they should continue not just for bladder cancer, but for all cancers.

Dr. Srinivas:

I think at our institution it's very similar. All therapeutic trials are still ongoing. If it's just a trial for blood collection, those trials are on hold. We've put a hold on opening new studies, but every trial that's open is continuing to enroll patients.

Dr. Srinivas:

There are some modifications that have been made and I think again like telemedicine and video visits there are a lot that are learned by this situation that's just been thrown at us. We are looking into consenting patients over the phone. These are all regulatory issues that are pretty unique to the situation. Getting patients to have blood draws perhaps not to just come into the center but maybe to go to a nearby quest or other places where they can get less exposure. All of these are things that are being changed again every week.

Dr. Srinivas:

We are looking into opening new trials as the situation eases up a little bit, and we are hopeful that in the next month or so we'll be able to at least get to enroll patients. I must say that companies have also come up with their guidelines and have all loved regulations in terms of taking deviations. Every one of these are a big deal in terms of execution of the trial. And I think this is all a complete new space and I think we are learning as we go along.

BCAN | Stephanie Chisolm:

Dr. Koo, are you doing any trials at Skyline?

Dr. Koo:

Yeah, we run probably eight to 10 clinical trials and probably at least four or five of them in bladder cancer space. It has been a viable response I guess from the trial sponsors. Their monitors are no longer visiting us, and so a lot of the activities have slowed down. There are actually some sponsors who said that they're not reviewing any new enrollment at this time, but it's not common practice across all sponsors. So some studies are affected more by others due to nature of study or due to the sponsor response. So there is a definite effect.

BCAN | Stephanie Chisolm:

Well, okay. So there've been a number of questions that are coming in regarding BCG. And I know you were talking about the SWOG trial still being open. One that's comparing the TICE strain of BCG and the Tokyo strain to see, again, if we can expand our opportunity to have more BCG of different variety in the United States.

BCAN | Stephanie Chisolm:

Do you know if there are any other studies or work being done on checking some of the other treatments that we have, whether it's oral chemotherapy or any other treatments that are going more to an oral option that might be able to be available to the bladder cancer patients, where they wouldn't necessarily have to come in for the actual procedures in the offices? That was a question from our audience.

Dr. Daneshmand:

Yeah, I think that's a great question and the trial is coming, unfortunately it's not quite open yet, but there is a trial for patients who have a specific mutation called FGFR3 that's anywhere from 20 to 40% of patients with non-muscle invasive bladder cancer will have. If they haven't responded to BCG and they've had adequate course of BCG, there is an oral agent that's forming.

Dr. Daneshmand:

But unfortunately those trials are on hold right now. They haven't opened, and we're hoping they'll open over the next six months or so. But right now there's no real oral option. Pembro, which is an immuno oncology, or immunotherapy drug was approved for CIS that's refractory to BCG, that is an option the patients most likely will receive that with their oncologist. So apart from that all the other treatments are intravesical and we are doing doublet chemotherapy agents for patients who are BCG nonresponsive. So gemcitabine and docetaxel being the most common.

BCAN | Stephanie Chisolm:

Dr. Srinivas is there anything you know of that's moving towards an oral regimen?

Dr. Srinivas:

I mean, I think for bladder cancer, the FGFR is the oral drug that we have for systemic advanced diseases.

BCAN | Stephanie Chisolm:

Okay. Dr. Daneshmand, you mentioned the CX bladder test, how confident are you with the scores on the biomarker tests that they are accurate so patients can feel comfortable with those answers?

Dr. Daneshmand:

Yeah, that's a great question, Stephanie. That test has been around for more than 10 years and there are more than six or seven published articles, and their results are very, very consistent for the last 10 years. We're very confident with the results. It's really a negative or a rule out test, meaning that the negative predictive value is very, very high.

Dr. Daneshmand:

And if it does turn out not to be negative, I don't like to call it positive because positive doesn't necessarily mean that you have cancer. But if it is not negative, then the patient should undergo the usual sort of workup. So we rely on that negative predictive value to tell the patients, "You're okay, there's a 98% chance you don't have cancer."

BCAN | Stephanie Chisolm:

So do you think there's any particular medicines? This is a question that I'm going to just make a general question that puts patients with bladder cancer who are on those treatments at an increased risk of either acquiring COVID-19 or having a really bad case of it, because their immune is compromised. Are there any treatments out there that you think might put patients at an increased risk from COVID-19?

Dr. Daneshmand:

Certainly nothing from our perspective. There's no evidence that any of the bladder cancer treatments put patients at increased risk or put them at an immune compromised state. Interestingly BCG vaccination in and of itself has become a potential vaccination and not intravesical form. But there's some very interesting correlation between patients who got vaccinated as a child and in countries like India, Japan, Brazil, Mexico, where as a child you get vaccinated. The incidence of COVID-19 within those countries do really make difference. This has led to some looking into the mechanisms of BCG and whether it confers an innate immunity against viruses such as a COVID-19.

Dr. Daneshmand:

So there are two clinical trials that I'm aware of and one that may be opening here that actually are vaccinating healthcare workers in the Netherlands and Australia to see whether they can reduce the actual acquisition of the virus to begin with. So the short answer again is there's no treatment that we're aware of. I don't want to comment on systemic therapies.

BCAN | Stephanie Chisolm:

Dr. Srinivas or Dr. Koo do you have any additional thoughts on that?

Dr. Koo:

I think Dr. Srinivas probably should address the issue obviously with chemotherapy and I think she did already, but just commenting on chemotherapy obviously causes immuno compromised, and so the risk of COVID virus possibly could be increased in that scenario. It's always needs to be weighed against delaying the chemotherapy and what the risks are. So it's really kind of the same issue.

Dr. Srinivas:

Well, I would say that we know chemotherapy decreases your neutrophils in the short term and that clearly predisposes people more to bacterial infection. We don't necessarily think that giving people chemotherapy is going to make them more vulnerable to the virus itself. But I think it's more the exposure to people, especially because we know that patients or people who are asymptomatic also be transmitting the virus.

Dr. Srinivas:

I think the concern more is that patients who are getting chemotherapy are going to be coming into the facility where they could get exposed. I don't think it's so much about chemotherapy, making people more vulnerable to getting the virus. It's usually patients who are on long-term bone marrow transplant who have such prolonged periods of myelosuppression who will worry about long-term viral infections.

Dr. Srinivas:

So I think in the short term for the patients who are giving for bladder cancer, we are not so worried that the chemotherapy per se is going to put them at a higher risk. But it's all these other things that we don't have a vaccine, we don't have a treatment, we don't have them. We don't want them to have this increased exposure to people without masks, without any protective equipment that they may be vulnerable to getting this virus just like anybody else who's not on chemotherapy.

BCAN | Stephanie Chisolm:

So practicing the universal precautions and following the CDC guidelines about social distancing and wearing a mask and all of those things are really important. Do you know of anything else that patients or their families could do nutritionally or exercise, whatever else they should be doing to stay on top of their health and stay in better shape so that they're less likely to succumb to COVID-19 if they were to be exposed. Is there anything that you're seeing that seems to be beneficial?

Dr. Srinivas:

We know all of the things you mentioned I think are really important. The hand washing, the usual ones that we tell patients. In this period of increased anxiety, I think taking care of your mental health, doing yoga, doing physical activity, trying to get engaged in things so that we are not inundated with all of this information that we have so little control over, I think is helpful.

Dr. Srinivas:

There are some information about vitamin D and its beneficial effect, at least in terms of outcome. Again, I think most physicians are somewhat uncomfortable about making statements, because we are so used to making statements based on large volumes of information based on level one evidence. Since information is just trickling along, it's somewhat anecdotal, but I think some of these general guidelines will apply in all of these clinical states.

BCAN | Stephanie Chisolm:

As you mentioned, the vitamin D, going outside and getting a little fresh air is probably not going to hurt anybody as long as you're six feet away from your nearest neighbor and you're wearing a mask, you should be doing okay and maybe it'll help your mental health and keep you in a more positive place I suppose. So this has been incredibly informative. Thank you all so much. Are there any closing remarks that you care to share? Dr. Daneshmand?

Dr. Daneshmand:

Stephanie, I want to really thank you for doing this. I know on the minds of many of the patients, I think they really benefit from hearing bladder cancer experts' sort of talk about these issues and the worries that come up. So thank you for organizing this. It's very, very helpful.

BCAN | Stephanie Chisolm:

We're very pleased to be able to do this and we can't do it without your help. I really do appreciate all of you jumping on this call and it was challenging to get everybody in the same place, but thank you so much for joining us. Dr. Srinivas, any final comment?

Dr. Srinivas:

No, I completely agree. Thank you to BCAN, and thank you for inviting us to be part of this amazing program. I think for most of us knowing information coming along is very helpful and we are learning from our colleagues, we are learning from our patients, we are learning from people who have had experience with this. So sharing this information and passing it along to our patients and to our colleagues is extremely important. So thank you for hosting this.

BCAN | Stephanie Chisolm:

You're welcome. And again, as you mentioned, there are registries that are looking at patients who have been exposed or who have been diagnosed with COVID-19, that also have bladder cancer. There is a registry that your doctor can enter you into, is that correct?

Dr. Srinivas:

Yes.

BCAN | Stephanie Chisolm:

So patients don't do it themselves. Their doctors will enter them into the system so that they're part of that registry.

Dr. Srinivas:

Every institution is doing it.

BCAN | Stephanie Chisolm:

Okay. Excellent. And again, we will learn so much more, the more people who participate in these studies are going to really help us have a better understanding. So Dr. Koo, any final comments?

Dr. Koo:

Yeah, thank you obviously Stephanie and BCAN for sponsoring this event. I'm an optimist by nature and it seems like, at least in California as well as elsewhere, the curve is starting to flatten and we'll probably maybe in a month just start have a gradual roll out of normalization. And so obviously healthcare and all these patients who are deemed to not have urgent or emergent issues really should come to the forefront.

Dr. Koo:

And by that time, so hopefully would not have to delay the care sufficiently to have caused any long-term ill effects. But more so, there's always silver linings, and that’s a telehealth issue. Who wants to drive an hour to the doctor's office, sit in the waiting room for an hour? Essentially spent half a day, when he could be taken care of with a 10 minutes call? So going forward, I think we're going to be better and stronger.

BCAN | Stephanie Chisolm:

Thank you and thank you all so much. We appreciate everything that you're doing every day in the trenches as we muddle our way through this pandemic. For those of you who are on this call, I want you to know that we do have some frequently asked questions. If you visit our website, bcan.org and you look for COVID-19 FAQ, you'll see that on the home page and you are welcome to check there.

BCAN | Stephanie Chisolm:

We will keep them updated as we learn more as we go through. I'd like to thank everyone for joining the program today. Please be sure to complete the short evaluation that you'll be getting in a day or so, and I hope that everybody stays healthy. Thank you all so much for joining us.

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