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

This program was recorded on June 8, 2020

BCAN | Stephanie Chisolm:

I welcome everybody to **Bladder Cancer and COVID-19: What Patients and Families Need to Know**. This is our June update. We've been doing this periodically, and I think it's really important to keep patients apprised on what's happening around the country.

I'm really delighted to say that I'm joined by patient advocate Rick Bangs, he's a SWOG and BCAN patient advocate; Dr. Ashish Kamat, a urologist from MD Anderson Cancer Center; Dr. John Gore, who's also a urologist from the University of Washington and Seattle Cancer Care Alliance; Dr. Seth Lerner, a urologist who's on BCAN's board of directors and is at Baylor College of Medicine; Dr. Neal Shore, who's a urologist also on BCAN's board of directors and is in practice at Carolina Urologic Research Center in Myrtle Beach, South Carolina; Dr. Gary Steinberg, who's the chair of our Scientific Advisory Board, who's there in New York City, and he is a urologist; Dr. Laila Woc-Colburn, who is an infectious disease expert in Baylor down in Texas as well; Dr. Singh, who is a medical oncologist from the Mayo Clinic; and Dr. Rob Svatek, who will be joining us shortly by video, who is a urologist from UT Health in San Antonio. I'd like to welcome you all and thank you so much for helping us keep patients informed during the COVID-19 pandemic.

BCAN | Stephanie Chisolm:

I'd like to just start with Dr. Woc-Colburn and just ask you, if you can, as an infectious disease expert, give us a quick update on what's going on. What are we seeing? What are we able to recognize already in COVID-19 and cancer. But if you have any specifics for bladder cancer, what are you seeing out there?

Dr. Woc-Colburn:

Thank you for having me over. So COVID-19 just celebrated its birthday, it's five months old, of what we know. In those five months, we have learned lots. There's lots to learn because each day gives us a new insight.

The first five months, like anything, is a learning experience. We learned a lot about manifestations, what to do, and also prepare our clinics of what to do next. And so, we're now in the phase of how can see our patients back into clinics safely? How can we continue doing procedures safely? Because we know that until there's a vaccine, we're going to have to be in the new normal. The new normal is wearing a mask so we can actually keep people from getting infected from people or infecting others, keeping that social distance, and washing our hands.

So that's the new normal. You're going to see that as you go and see your doctor, that there is going to be some distancing. Some of them might have a barrier from the person they're treating. You might have to go and get an extra test before you come to make sure you're not infectious. So you can transmit it to the people who are doing the procedure.

Then what does it mean to your immune system? As bladder cancers, you have a cancer, so the immune system might not respond as well. But it's not what we call a liquid. It's not a leukemia, it's not a transplant. So you do have a risk factor. It might be also because of age. But it's keeping the norm of keeping away from those part. Once the vaccine comes, be available to take it.

BCAN | Stephanie Chisolm:

So we are going to talk a little bit about vaccines and, in particular, one that's using some BCG at the end of this program. Do any of you have any comments that you want to make as far as things that Dr. Woc-Colburn had just explained, where we're seeing, where we're going. I have specific questions that I'll follow up with. Anybody have any comments?

Dr. Singh:

Yeah, I think this is a new normal that all patients and physicians have to cope up with, and then understand and make things safe for both the providers and the patients. We need cooperation from the patient side, understanding that they may have to come in for extra tests before their visits.

Also, they may not be able to bring in their loved one for their visits. They may need support or advocates maybe on the phone when they are in the clinic. So they need to get used to all this new way of taking care of them.

Everybody's learning. We are learning. We are getting used to virtual platforms which are not perfect all the time. Families are learning how to deal with all of the problems in a different way. Everybody's learning. So we just need cooperation from everybody and understanding.

BCAN | Stephanie Chisolm:

Absolutely. I think that that's really important, because I know patients feel a lot of stress over their diagnosis and not being able to get care. But they do have to realize that you all are working so hard to make sure that they can get safe care, and that's really important. And knowing those additional tests, even just coming into the hospitals.

I think in some locations, correct me if I'm wrong, patients are allowed to have family members that can come into the hospital and others no. You can't bring anybody in with you, which is really a challenge. Is that the case? Are there some of your institutions around the country where they can have family members come in when they come in for procedures or the hospital space? Dr. Gore?

Dr. Gore:

Yes. We opened up two weeks ago to visitors. So for the first two months of the pandemic, if you had major surgery, if you had a radical cystectomy, you had to recover in the hospital by yourself. Your loved ones were allowed to come in for one stomal therapy visit. Sorry about that. One stomal therapy visit and at discharge. But we've opened up and now you can have one caregiver or loved one stay with you during your inpatient stay and you're allowed to bring one person with you to a clinic visit.

BCAN | Stephanie Chisolm:

Those people often probably have to go through COVID testing before they come in to the hospital or no?

Dr. Gore:

They don't. Everyone gets screened and, as been mentioned, we have a universal masking policy. So we're masked, the patients are masked, and their visitor is masked. We do universally test for COVID our surgical patients, and that's just because we know that the surgical outcomes for COVID-positive

patients are pretty terrible. But the universal masking reduces the bidirectional risk for the clinic visits and for the inpatient visitors.

BCAN | Stephanie Chisolm:

If the patient's coming in for just a routine visit, are they expected to have a COVID test, or just having their temperature checked and fill out a questionnaire to see if they have any symptoms? Is that what we're seeing going on around the country, or is this something where everybody has to have a test before they can come in to see their doctors? What's going on?

Dr. Woc-Colburn:

So if you come to the hospital, or even if you come to a clinic, you're going to get the routine screening. So you're going to get questions asked from the screening, have you been exposed, and have your temperature checked. Then use some alcohol to clean your hands.

Now the people who are being tested are those that will require a procedure. That's how the infection control have done that. I think that's pretty standard not just here in the US, but globally. If you're going to have a surgical procedure that requires ... A colonoscopy, a cystoscopy, or even a dental exam, like we have a deep cleaning, they're going to require SARS-CoV-2, so some testing.

But if you're going to come and visit someone in the hospital, it's just questions and a mask. The mask actually reduces the transmission up to 75%. If you wear a mask and someone else wears a mask, the reduction rate of being able to transmit it is looking like more than 75%.

Dr. Kamat:

That, obviously, as you recognize, varies from institution to institution, because at MD Anderson, which is right across the street, we are testing every new patient that comes in and anybody that is having any sort of intervention such as surgery or even initiating chemotherapy. So we're just not relying only on questionnaires, but we're also actually testing every new patient or every new patient starting a new treatment.

Dr. Singh:

So for Mayo Clinic, the policy had been very fluid. In the last three weeks, we have seen three different iterations of the policy already. It's quite possible, with the increasing number of infections in Arizona, which we saw after the opening at Memorial Day weekend, there could be further restrictions coming on. At this point, as of today, the last recommendation is to check for COVID PCR prior to every cycle of the chemotherapy, within 72 hours of every surgical procedure requiring anesthesia.

For patient's family members, only the questionnaire, which they have to fill in, and a temperature check at the clinic. But patients coming in for routine follow-up where there is no procedure or no chemotherapy, they are not being tested at this point.

BCAN | Stephanie Chisolm:

Dr. Steinberg, you're up there in New York. Obviously, you're still dealing with the aftermath of being hit so desperately hard. What are you seeing now that you're opening up a little bit for some business? What are you doing for testing patients in New York?

Dr. Steinberg:

Yeah, I think that New York, in general, is cautiously optimistic. I think that the brunt of the infection is ... We've passed. The death rate in New York State is much, much, much lower than it ever was. There was a time period where we're 800 deaths per day. We're well under 50.

Every patient that's going to have a procedure, every patient getting chemotherapy or immunotherapy is being tested. All the physicians are being tested. All the staff are being tested. Everybody who comes into any NYU facility has to have their temperature taken and fill out a questionnaire. We can do that on our smartphones before, every morning before we go to work, taking temperature, filling out the questionnaire. If we don't pass the test, we're not supposed to come to work.

One of the issues that I'm still very concerned about, and a lot of patients are still concerned about, is visiting and can family members come. The policy is still relatively fluid. We're hopeful, I'm hopeful, that with additional testing that we'll be able to have patient family members come to visit.

One of the issues, as we know early on, was the lack of testing in New York. At NYU, anybody who wants a test can get a test, we're very actively testing, as well as doing the antibody test for the faculty. So we've made tremendous strides. Issues about family members visiting or coming with family members is still an issue, but we're open to surpass that soon.

BCAN | Stephanie Chisolm:

Dr. Shore, what are you seeing in the community and hearing from your colleagues in some of the large urology practices? Are you seeing anything different?

Dr. Shore:

No, not really. I think it's very consistent with the area in the country that correlates with your infectivity rate. We've been pretty fortunate in South Carolina. We've had one of the lower rates of infection. But we've pretty much done what's all been described. Now we're offering testing to anybody undergoing any type of invasive procedure, outpatient, inpatient surgery. Not doing it routinely for clinic or systemic therapy administration.

I will say we're talking about it, but at the height of all this, and I'm sure that our colleagues who were really hit hard, is this is really quite a tragic experience for families when they could not have their family members attend them in the hospital. This was quite an astounding thing that I'd never seen before.

I actually had patients who really were more moved towards hospice care than on some interventions because of the fear of being alone and family members. So this was really truly an amazing experience, I think, that we've all had to endure.

BCAN | Stephanie Chisolm:

I think that's very telling in its evolution. I think we're going to just keep learning as we go through and as people become more comfortable. Then who knows what's going to happen as people are very comfortable in going out and about without masks and we see any kind of resurgence and things like that.

Well, let's switch a little bit and talk a little bit more about urgent/emergent treatments. If regular treatments that are being scheduled are requiring testing, what are you all doing for urgent/emergent treatment? Dr. Lerner, what is going on? If somebody has an urgent case that they need to be seen right

away, how do you work with them to make sure that they're not COVID-infected? Is there something that you're doing there?

Dr. Lerner:

So if you're referring to, say, an outpatient surgical procedure or an inpatient surgical procedure and we, as I suspect most other institutions, have rapid testing, obviously the thing we have to do first and foremost is take care of the patient.

If, for whatever reason, you can't get a test back or you get a test back that's inconclusive, I personally haven't been involved in that, but we would treat the patient as if they are positive, take all the necessary precautions and then do appropriate testing of the folks that have been in that environment. First and foremost, our responsibility is to patient care and obviously protecting all of the patients and the staff that are involved.

In the clinic, we're not doing rapid testing, but I think that we're all prepared to do the same thing when those things come up. Fortunately, true urologic emergencies are generally dealt with in the hospital. There are a lot of things that we can take care of in a clinic.

I think that the message is to not avoid the clinic, quite frankly. We're open for business, we've been that way for several weeks, and we want people to feel comfortable coming in in a time of need, whether it'd be a new patient or an established patient or a post-op patient maybe that's having difficulty with a catheter or an infection.

Please do not put those things off. We're all prepared to take care of the patient, take the necessary precautions if there's a risk of COVID-19 or, for that matter, any other infectious illness.

BCAN | Stephanie Chisolm:

Dr. Svatek down in San Antonio, are you seeing anything different down there?

Dr. Svatek:

I'm just hearing the other providers talk. I think we're pretty similar to Houston. We don't do regular testing for procedures in the clinic just to confirm that. Cystoscopy, for example, where I'm at requires testing. We do screening in the clinics.

We are also encouraging patients to keep appointments, but we're also really strongly leaning toward telemedicine visits. A large component of our practice is through video visits, and a large part of that is because of the spacing issue in the clinic itself, trying to limit the number of people that are actually on the elevator and in the waiting room.

And so, we're trying to capture patients and reach out to them to let them know that it's okay, that they need to make their appointment, and we have alternatives rather than in-person visits.

BCAN | Stephanie Chisolm:

We were going to talk a little bit more about some of those alternatives in terms of telemedicine and some other things that are going on outside in just a moment. Dr. Singh, as a medical oncologist, if somebody's having a problem right away, is there any other precautions or information you think we should share with them in terms of things that would require them to get to the emergency department? What should they be aware of? Any other advice?

Dr. Singh:

Yeah. So from a medical oncology point of view, essentially the main problem that patients can have is infections related to chemotherapy. Neutropenic infections can be life-threatening and are emergent problems that need to be dealt on an emergency basis. We are guiding our patients to do inform us and proceed to the emergency room if they have fevers after they have received chemotherapy, which is the standard protocol. However, when they come to the hospital, they are presumed to be COVID-positive. So the emergency room are prepared to handle patients coming in and they are immediately isolated and tested. They stay under the presumed COVID-positive umbrella until the test comes back, which now has a quick turnaround time. At the Mayo Clinic, the turnaround time for the test is around six hours. And so, they are able to find out if the patient has COVID or not.

But, otherwise, for routine infections, they are advised to immediately come to the emergency room, especially after hours or, if it is in the morning, we are open to see them in the clinic and triage accordingly.

The other issues that the oncology patients are facing are immunotherapy-related complications. There are patients coming in with pneumonitis, which is inflammation of the lung associated with immunotherapy, which can confound with findings of COVID infection in the lung. Those are patients which are a little complicated. [inaudible 00:21:55] is not very clear yet how to proceed with.

Again, they are being admitted and started on steroids, but at the same time being worked up quickly for COVID to make sure we are not giving them steroids on top of having infections.

But at the same time, in my own practice, I have seen patients who had routine follow-up scans for the tumor assessment and we found findings suggestive of COVID infection, and they later turned out positive for COVID infection. They were asymptomatic at the time of the scan.

And so, this is all new, as I said before, and we are learning the process. But the hospital systems are now, I think, in a position to handle emergencies safely and keep our patients safe.

Patient Advocate | Rick Bangs:

Stephanie, may I ask a question?

BCAN | Stephanie Chisolm:

Yeah, please.

Patient Advocate | Rick Bangs:

Yeah. I'm curious, from the family caregiver point of view, whether there are specific guidelines that are provided before they come in for what they can and can't do while they're in the clinic, or from a COVID-influencing management of care for patients for side effects or surgical recovery? Are there no changes to any of that from a COVID point of view?

Dr. Singh:

From a medical oncology point of view, this is now a standard part of the conversation of treatment logistics and outcomes for patients who are receiving therapy. For every patient, I am having a conversation regarding chemotherapy. As I talk about the risks of chemotherapy, I talk about the risk of having complications in case they catch COVID during chemotherapy.

Dr. Singh:

I'm sure surgeons and Dr. Lerner and Dr. Shore can elaborate on it, how they are having a conversation regarding risks of COVID before or after or immediately after the surgery and its impact on the outcomes.

BCAN | Stephanie Chisolm:

Okay. Well, good. Along those lines, when somebody has had a COVID infection, I know we've alluded to this earlier, Dr. Woc-Colburn, is there anything that's out there that says you should wait a certain period of time before you should go in for any kind of a procedure that requires you to have anesthesia, or anything else in particular that we've learned already that would limit what patients are able to do for their healthcare based on having had a COVID experience?

Dr. Woc-Colburn:

It's going to depend from area to area. I mean as the COVID has become more in the community, we know that we can pick it up. One of the things is trying to avoid large crowds or poor-circulating places because you're more likely to get it.

Dr. Woc-Colburn:

If you have a procedure, I mean what we have from the CDC is testing before. We've heard what MD Anderson does, what Mayo Clinic does, and the other places, but you'll have some prior testing before you have the procedure.

Dr. Woc-Colburn:

The temperature checks is because we know that as the virus is in our body, our temperature goes up, and that's probably [inaudible 00:25:31]. If you're experiencing loss of sense of smell, upper respiratory infection, cough, not feeling well, maybe you don't want to do the procedure that day. Inform your doctor, get tested, and then just delay that a little bit, but not too much, because it is important to get the procedure done.

BCAN | Stephanie Chisolm:

Okay. What about after somebody did have an infection, though? Dr. Steinberg?

Dr. Steinberg:

Well, I mean, again, I think that as we come back and forth over and over again, I think that getting tested and the availability of testing is critically important. Unsure yet of the role of the antibody test, but certainly the RNA test is critically important.

In New York, if you're COVID-positive, we're delaying surgery for at least two weeks. Unclear on the relevance of getting another test. This is for an asymptomatic patient. If you're a symptomatic COVID-positive, you wait four weeks before any procedure. Again, unclear of the benefit or relevance of repeating that COVID test prior to a procedure.

BCAN | Stephanie Chisolm:

So after recovery then, though, is there anything that patients should be aware of? Because I just feel like there's going to be patients after patients perhaps on this call who've had COVID-19. What should they be aware of as far as getting back into their regular treatments? Is there a concern because they've had the COVID?

Dr. Steinberg:

So if they're symptomatic, we're waiting four weeks after recovery. If they're asymptomatic, it's two weeks.

Patient Advocate | Rick Bangs:

So symptomatic, Dr. Steinberg, would include a lingering cough from COVID? I had it four weeks ago. I've still got a lingering cough.

Dr. Steinberg:

Yeah. I mean any of the signs or symptoms that we're associating with a COVID infection and then a positive test, waiting until you're asymptomatic, and then four weeks from the last day you had those symptoms.

BCAN | Stephanie Chisolm:

Okay. Have you seen any impact on people being afraid to come in when they've had symptoms and they haven't yet been diagnosed with bladder cancer? If they are eventually coming in, are you maybe seeing diagnosis at a more advanced stage? In some people, it hasn't been that long. But what are you seeing?

Dr. Steinberg:

I believe so. I mean I just did a TURBT on a patient who initially we saw in the January period gross hematuria, and high risk for muscle invasive. If he did get a COVID infection, there would have been poor outcome, delayed. Even when things were loosening up, we need to get you in to make the evaluation.

Interestingly, CT scan showed a mass in the bladder, but did not look all that significant. When he had his TURBT finally about four to five months after that initial CT, he had multiple sizable tumors in the bladder of which one was clearly muscle-invasive, the others were deeply invading the lamina propria. I think that there's no question that was a significant delay.

I had another patient that I did a cystectomy on, who we added an extra two months after the completion of his neoadjuvant chemotherapy. So he would have had surgery in April, didn't have surgery until later in June, and had T3b disease.

Again, would he have had T3b disease anyway or was the added delay? We all believe that when you add significant delay on some radical cystectomy and muscle-invasive disease, there are risks for adverse pathology. Then in the patients with recurrent disease, I've seen ... Have more tumors than we would have expected because of an additional three-plus months delay.

Dr. Steinberg:

You have to remember, however, that New York, New York is really quite a different place than anywhere else in the United States, consistent with what we saw in Milan, in Spain, and then part of Great Britain and Paris, where we had thousands of patients. The NYU system, which is just one system in a large city, we were running with 900 patients in the ICU on ventilators consistently for a good three to four-week period there.

BCAN | Stephanie Chisolm:

That's pretty rough. Any other thoughts on that? As far as people that weren't able to get in for testing, are you seeing that they're showing up now even though they might have had symptoms three months ago? Now that you're able to get in there, are you seeing more advanced stage, I mean, that you're seeing elsewhere? Dr. Gore?

Dr. Gore:

I think, to some extent, it's still a little too early to tell. I think that we're going to learn more in the next two to four months about treatment deferrals. I think one of the things that is happening is that our patients not only aren't seeing us for care, but they're not seeing their primary care doctors for care, they're not going to the emergency room when they have abdominal pain.

Dr. Gore:

I don't know if that's happening for hematuria, but, for example, our emergency room was down 60% relative to pre-COVID capacity just because people weren't coming in for non-COVID-related emergencies. We do have some incidental diagnosis of bladder cancer, and even patients with hematuria, we don't know what their prevalent behaviors have been. So I do have some patients that defer their own care due to COVID fears, and I think the story is still yet to be written on them.

BCAN | Stephanie Chisolm:

Right, right, right. Certainly plenty to look forward to reading and learning from as these things get to our peer-reviewed publications and we begin to incorporate them into our learnings and our teaching.

So what are you seeing that's been if you want to think of it as a bright light in COVID-19 in the sense of there have been some changes to things like telemedicine and other things? What are you seeing that you hope were going to stick around that has been a real benefit, switching over to, say, oral agents for chemotherapy or delegating to more local care? Perhaps the trend we'd like to continue? Is there anything that you've noticed across the board?

Dr. Steinberg:

Well, one of the simple things is that hospitals today have never been so clean. I mean they are spick and span and that there's a huge effort and resource put out there to keeping the hospitals and the doctors' offices cleaner than they've ever been.

Dr. Steinberg:

I mean in the old days, it was kind of we've paid almost lip service to it. Now you can really feel very, very comfortable that you drop something on the floor in the hospital today, probably okay to pick it up and eat it because the hospitals are really, really clean. I think that we are practicing universal precautions that before we weren't. So just something as simple as that, that's a major change for the benefit of the healthcare workers and the patients.

Dr. Woc-Colburn:

I would second that, Dr. Steinberg. I mean I can tell you that our rates of C. diff and hospital-acquired infections are lower because we are actually washing our hands more than we want to. But, yes, I think that is one of the benefits and, yes, the places look spick and span.

Dr. Shore:

I think you're absolutely right, Stephanie. At least there've been several silver linings. I think one of the biggest ones, and it was mentioned earlier, is this development of virtual medicine or telehealth, telemedicine. I think it's fantastic, and fantastic in several ways.

So many of the times, patients really who were established patients, not a new patient but an established patient, who has a cancer diagnosis or not, really does not have to be subjected to coming into a healthcare provider's clinic, the travel, the time, wearing the mask, subjecting themselves to other folks, and then our healthcare provider team being potentially subjected to them, when really all we need to do is say, "How are you feeling? Are you having any symptoms? More importantly, let's review your recent imaging or review your lab work."

I find that patients really love this convenience. I've enjoyed it. It's an interesting opportunity to have a meeting and dialogue and look into where they live, where they're calling you from. I'm having appointments from people in their homes, but some folks are calling me while they're out doing their normal activities. It's quite positively entertaining around all of this negativity.

But at the end of the day, I think it provides a safety from exposure and I think it provides a tremendous efficiency in our healthcare system, that [inaudible 00:35:50] stacking up people in waiting areas and getting all crowded when all you really needed to do was call and say, "Yeah. Hey, you know what? I am doing really well and the medication I'm on is working," and then reviewing the labs and the imaging. That's actually a pretty quick call and it's efficient for everybody.

There's a lot of things I could list, but you mentioned it earlier, Stephanie, is home testing. There's a real industry of markers and lab testing, whether it'd be urine test or blood-based testing, that can be done in the home, and organizations that will facilitate that. Sometimes it's just a mailer. It could be a saliva test. It can be a urine test.

I think this is going to really revolutionize even more the efficiency of how we deliver healthcare. For many of us who see our third opinions, it's a great opportunity for my colleagues in the major academic centers when people can call in and say, "Hey, I don't have to necessarily be in Georgia and fly to New York or Minnesota or Texas, and I can have my appointment."

Dr. Shore:

This is really a rather remarkably important development. I hope that the legislators don't let it slide back into some of the regulatory impediments that prevented this. This is where patients and an organization like BCAN can really help legislators understand the importance of this.

BCAN | Stephanie Chisolm:

Dr. Lerner?

Dr. Lerner:

Yeah, one of the things that I've observed, and I know that Dr. Kamat and Dr. Woc-Colburn have probably seen much of the same thing, is the extraordinary level of collaboration between institutions that are often in competition with one another. In Houston alone, as in New York City and Chicago and many other major cities, all of the organizations really have shown truly an extraordinary level of collaboration to solve common problems and learn as we go.

I think that has been extraordinary to see, but the obvious challenge is to keep that spirit and that level of collaboration moving forward. We all have a common goal and a common purpose. It's been really a lot of fun to see how our leaders have stepped up, and we've all learned from each other.

You'll hear at the end from Ashish new alliances, new uses for old and current drugs, and how this crisis, this global crisis, has really spurred such a high level of innovation that you can't help but hope that it will have a very positive impact on all aspects of healthcare, from treatment to delivery to prevention to everything. It's really the communities and our political and healthcare leaders to leverage all of this to create a better environment for healthcare and our patients in the long run.

Dr. Steinberg:

Getting back to the surveillance issue, a lot of the way we survey patients that have already been diagnosed is really based on what we used to do and empiricism and not a lot of evidence-based medicine. And so, for a young person who's computer/electronic-medically savvy, this is going to be a gold mine of data because most of the healthcare systems in the United States have electronic medical records.

It'd be interesting to see, take, for example, all of our non-muscle-invasive bladder cancer patients that did not have surveillance cystoscopy every three months and have it every six months of five months or 12 months and so forth and you try to draw some correlations on who is safe to do that on, who's not safe to do that on, and potentially change our paradigms and our algorithms of how we follow patients, save money for the country potentially, save time and energy for the patients, and actually provide evidence-based care and better care, which I think would be a major benefit.

So data mining is going to be a major scientific endeavor for everybody in the very near future because we're going to have a mountain-load of data to look at to try to get some answers on how to not only provide better COVID-19 care, but better care in general.

BCAN | Stephanie Chisolm:

Great. Thank you. I see that we have a few questions that are coming in from the audience, and I did want to just touch briefly on the status of bladder cancer clinical trials. Then also get a quick update on the BADAS clinical trial where BCG is being used as a vaccine.

So since all of you are so engaged and such heavy researchers, tell me how is your research on other aspects, not COVID-19 aspect. How is it continuing? Has it been paused? Are you getting back up and running now that things have settled down a little bit? What's going on in the research phase in bladder cancer from what you're seeing across the country? Dr. Svatek?

Dr. Svatek:

Yeah. So I think it is fluid in initially we shut down almost completely, although people that were on clinical trials, getting drug therapies, we were able to continue those. But now, fast forward to June, we are almost running back at full speed. We've had some challenges with certain things, and certainly we had to be more flexible with follow-up regimens, surveillance regimens, delays, and things like that.

But I would say my experience has been that patients on trials are eager, had been eager, to continue. I only can recall one or two that actually came off trial because of COVID. The workers surrounding the clinical trials, the team, really has invested a lot into what we're doing. I felt like even when we were forced to go home, I had team workers that were just trying to do as much as they could at home to keep things running smoothly.

So my experience has been that I was very impressed, both from the patient's perspective and the provider perspective, on how the trials were maintained during that time. Nowadays we are thinking differently about how to open trials up to do more distal connection. But, overall, my experience has been really remarkable.

BCAN | Stephanie Chisolm:

Okay. Anybody else? Dr. Singh?

Dr. Singh:

Yeah, I can chime in. Same as Rob. Clinical trials, we did see an acute drop in enrollment and also availability immediately as the search came on in early March. But then, since then, things have settled in and there has been a wave of changes which came through the sponsors and also NCI regarding the clinical trials being run through NCTN cooperative groups to make the care of the patients on clinical trials more realistic.

So the patients that were coming in for their quality of life checks or questionnaires or just medication reconciliation, those are being done virtually by the clinical research coordinators on the phone or on virtual, for consenting process has become more virtual.

Many of these new strategies have been incorporated and being allowed by the sponsors on the clinical trial, where non-clinical trial information visits can be done by local providers in guidance with the institution, again, to make the life of the patients on the clinical trial follow-up easier.

Dr. Singh:

So with that, what we have seen in clinical trials, in the bladder cancer at least, Rob can attest to it, and I'm running the 1806, the accrual, where the initial blip has gone back up with the help of all these measures that we have taken in, those patients essentially need to be taken care of and, if they need access to clinical trials, we are working hard to provide them the access to the clinical trials in a safe way.

BCAN | Stephanie Chisolm:

Great. Any other thoughts before I ask Dr. Kamat to talk about the BCG as a vaccine for COVID-19 trial? No? Dr. Kamat, what's going on with the BADAS trial?

Dr. Kamat:

Oh, so I just want to echo what was just said. I think when COVID-19 hit us and our patients, we all rallied together. But, anyway, so we all rallied together, and one of the things that happened was BCG researchers, folks that have done immunotherapy, BCG, for decades as vaccination against tuberculosis and other viral diseases reached out to us urologists in the United States because of our interest and ability to provide our patients with BCG.

It really was quite remarkable how the whole community came together. I know I reached out to you, Stephanie, and you, Rick, and a bunch of other patients because we wanted to share with you the fact that BCG, which we use here for bladder cancer, potentially could be used as a vaccine for healthcare workers, law enforcement, and then eventually other folks as well.

Everybody was very supportive. The whole medical community came together. Dr. Lerner, who's at Baylor College of Medicine, myself at MD Anderson in Houston, we rallied together, folks in California, in College Station, in Boston.

So the BCG study essentially is BCG as defense against SARS-CoV-2. It is essentially to see if BCG ... And there's the background. You can see that there. It's essentially to see if BCG can help decrease the severity of the COVID-19 infection.

So we're not proposing that it will abrogate infections in general, but because BCG ramps up Th1, suppresses the cytokine storm in theory, we expect that the severity of the infection will be lower in subjects that are vaccinated with BCG.

So the trial is ongoing in the US. It's accruing healthcare workers in Canada. They're accruing law enforcement folks in the Netherlands and Australia. There are already up to 4,000 individuals that have been vaccinated.

So we don't have efficacy data yet, but the interim analysis of safety in the overseas arm has shown no adverse events. So stay tuned.

BCAN | Stephanie Chisolm:

Okay. Excellent. If you want more information, remember that we did an actual webinar specifically focused on BGG and this vaccine, and it's available on the BCAN.org website. If you click on COVID-19, you'll see all of our regional webcasts that we did about COVID-19 around the country, but you'll also see the BCG webinar as well. Any last comments before I open it up to questions from the audience that have submitted those questions? No?

BCAN | Stephanie Chisolm:

Well, I have a question right here as far as now that air travel is opening up a little bit, there's a question from a patient. How concerned should someone with radical cystectomy and neobladder be when they're continuing with immunotherapy right now if they have to travel? Because personal autos, airplanes, per excess of a thousand miles, if they have to go some place, should they be really concerned about that travel aspect with their immune-compromised system from being on BCG or another immunotherapy?

Dr. Steinberg:

Well, I think we shouldn't conflate chemotherapy with immunotherapy in terms of immunosuppression. There's clear potential for immunosuppression from chemotherapy. Immunotherapy much less. I mean immunotherapy, if anything, were taking the brakes off of the immune system. And so, I don't think that the risk of infection is significantly increased. Different than chemotherapy where it certainly can be.

So being on an IO agent, all of our patients at NYU, they're on IO agents, have gotten COVID-19 tested and are being tested. But I don't necessarily think that it puts somebody at an increased risk other than making sure that they follow universal precautions. The airlines, I think, are making a major effort for that as well.

BCAN | Stephanie Chisolm:

So all travel then in general. You're thinking not just people on immunotherapy, but just any bladder cancer patient that might feel the need or might have something that they really do feel they have to travel to. Again, following everybody else's guidelines, you think those are safe suggestions? Because there was another question specifically relating to travel that came in.

Dr. Woc-Colburn:

So I think it's safe as it can be. So there's measures being taken by the airline industry. One of our physicians just traveled to the east coast.

So it's, again, wearing a mask, washing your hands, probably take your Clorox, clean the area that is around. I mean the airlines want your business, so they probably are going to go the extra mile. But trying to also look at some of the peak hours or the peak times. So maybe not travel July 4th weekend because everybody's going to be traveling at the same time. You're going to have to look at other times. And you can see which airplanes are more crowded than others.

I do note that I have a couple of friends who are driving this summer, but they are cancer, leukemic patients, or Hodgkin patients that are going to drive, because they feel that they're going to have exposure. So it might not be a bad idea to explore the US in a car.

BCAN | Stephanie Chisolm:

Somebody's husband had to charter a plane from Key West to have a COVID-19 test before his cystoscopy next Monday, that the university would not let them send a driver to pick up a test kit and return it to the University of Miami.

This individual was wanting ... Was that a rational thing? Should they have been able to do a COVID test remotely? What do you think, Dr. Colburn?

Dr. Woc-Colburn:

Yeah, that is designated by institutional guidelines. So as a disclosure, I do know the person who runs infection control at the University of Miami, and I know she is very OCD about this. I mean I think it's how they feel about it and everything.

Is there a difference between LabCorp, Quest, or CPL? Probably not. For the test, we do know that some of them can give you false positives and false negatives. But I think it depends on the exposure and I think it's the institution-by-institution.

Dr. Kamat:

Yeah, I do want to touch on one thing. Most institutions are doing all this testing to protect the patient. So I would encourage the viewers not to look at it as a punitive event or the testing has been cumbersome, because we're really trying to protect the rest of the patients. If a patient comes in that is relatively healthy but is positive, a lot of our patients who are in the hospital getting active immunosuppressive therapy, for example, bone marrow transplant, are at a huge risk.

I would encourage people to be a little patient with these inconveniences. They are inconvenient, for sure, but each hospital follows the policy based on the risk to our individual patient population per se.

BCAN | Stephanie Chisolm:

Right. Very good point.

Dr. Steinberg:

It does vary by region. I know that it was in the paper today that New York is doing about 33,000 COVID-19 tests per day in New York State. I think that it's unfortunate, but that patients should be able to get a local COVID-19 test before surgery and not have to slide back and forth.

BCAN | Stephanie Chisolm:

Well, this is a really related question. There's an individual that needs to go in for quarterly CT scan and blood test. We know that the larger hospitals are seeing more patients that might be COVID-19. They were wondering, is it safe to do blood draws at the hospital or should they have them done elsewhere? What are you seeing as far as safety for the patient? Could they get tests done someplace else and then have those results sent to you at some of the bigger centers? What have you seen?

Dr. Svatek:

So I think maybe a couple of questions in one. I mean it will depend on the physician and the practice that they're in as to whether or not ... Where they allow the labs to be drawn at. But most of us will recognize labs, and imaging in many cases, done elsewhere under certain circumstances.

With regards to whether it's safer at a hospital or some outside clinic, I would say it depends. I mean some hospitals have things very well demarcated and things split apart so that actually getting the laboratory tests at the hospital may be safer.

Dr. Svatek:

So I think it just depends on what the alternative is. The things that you want to keep in mind is are they practicing social distancing? Are they screening upon entry? Those are the questions that you could ask before you go somewhere to investigate how safe it would be for you.

BCAN | Stephanie Chisolm:

Okay. That is a good point. Any other comment? I think we have time for just a couple more questions. Could a COVID-19 infection weaken the immune system of someone with non-muscle-invasive disease to make them more susceptible to a recurrence of their bladder cancer? We know that bladder cancer has a high rate of recurrence. Do you think a weakened immune system might increase the risk of recurrence? What are your thoughts on that?

Dr. Svatek:

Yeah. So I am not aware of data that would support that. COVID infection would weaken your immune system. During the actual infection, you're going to be weak and you're going to be susceptible to having other illnesses.

So during the actual infection, when your body is trying to fight the COVID virus, that period of time, yes, you're weak and, yes, you're vulnerable. But once you recover, I don't think that your immune system is weaker. In fact, it may be a little bit stronger. So I wouldn't think of it as weakening the immune system.

Now certainly if you suspect that you have COVID, you have symptoms or you're positive, during that period of time, until you recover, I would avoid ... And it's mandated by the place that you're at. I would avoid putting yourself in situations where you could be exposed to other things. So you must quarantine until your symptoms resolve.

BCAN | Stephanie Chisolm:

Any other feedback? No? One more question. Since immunotherapy stimulates the immune system, could it provoke a cytokine stream in COVID patients? If you're already on immunotherapy and then you were to get COVID, do you think that would be an increased risk because of being on the immunotherapy? Have you seen anything [crosstalk 00:58:30]?

Dr. Singh:

That's a good question. We are still learning through our experience with this disease in patients on immunotherapy. We here at Mayo Clinic have not seen any complication in our patients. We're eager to listen if anybody else had a similar experience at other institution.

BCAN | Stephanie Chisolm:

So I think what's really important also is to check with the individual institutions that people are being seen at, because you guys are representing some of the larger institutions and even one of the larger urology practices.

BCAN | Stephanie Chisolm:

So I think you're all in agreement that everyone should confirm with the place where the patients are being seen, because there is such variability. Is that what I'm hearing from you guys? *All nodding* Okay, good. Just wanted to check on that.

BCAN | Stephanie Chisolm:

Any last comments before we end today's program? Mr. Bangs, do you have any other questions that we should have asked?

Dr. Steinberg:

I have a comment. We need to balance everything in our life, but we certainly need to not be afraid to seek and get medical care, medical attention if we suspect or do have bladder cancer. I think that the risk of not treating the bladder cancer right now in the United States greatly outweighs the risk of COVID-19 infection, especially because we learned so much about COVID-19 and we are practicing universal precautions and we're much more cognizant of risk. But there's no question that bladder cancer can be a life-threatening, life-changing disease and we should not miss our opportunity to treat it effectively.

BCAN | Stephanie Chisolm:

Well, I want to thank everybody. This has been a phenomenal update. I really appreciate it. I really recognize that this is a work in progress. We are learning every day. I think that COVID-19 has advanced practice and certainly the concept of telemedicine and so many of the more positive things that you have mentioned today on our call, that we will see some significant change.