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Expert Panel: What Is the Future of Early Intensification in Localized Prostate Cancer?

### Announcer:

Welcome to CME on ReachMD. This episode is part of our MinuteCE curriculum.

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### Dr. McKay:

I welcome it's a pleasure to be with you here today. My name is Dr. Rana McKay and I'm a GU Medical Oncologist at the University of California in San Diego.

### Dr. Agarwal:

Hi, my name is Dr. Neeraj Agarwal. I'm a Professor of Medicine and GU Medical Oncologist at the Huntsman Cancer Institute, University of Utah. It's a pleasure to be here.

### Dr. McKay:

Pleasure to be here with you, Neeraj, who is such a dear friend and colleague. So, you know, today we're going to be talking about high-risk prostate cancer, localized prostate cancer. And clearly these patients, while the majority of individuals are actually cured with local therapy, whether that be radiation or surgery, upwards to 30% of people with high-risk disease are at risk of increased prostate cancer mortality. And the current treatment paradigm for these patients is really suboptimal. And we as a field have been working to design studies to potentially escalate therapy for these individuals with the potential of potentially improving their long-term survival and actually curing more patients who have locally advanced disease.

And there's a couple of ways that we can tackle that strategy. There are obviously, you know, surgical-based approaches and perioperative strategies that can be utilized. There's also radiation-based strategies that can be utilized. With regards to the perioperative approaches, there are strategies of giving therapy prior to surgery, which is neoadjuvant therapy, and strategies of giving therapy after surgery, you know, adjuvant-based strategies.

And, you know, there's been a long history of a series of neoadjuvant and adjuvant-based studies that have been conducted previously for men with prostate cancer. And, you know, those studies were really limited, given a lack of really highly effective agents beyond, you know, ADT and chemotherapy. And the availability of ARPIs actually presents an opportunity to investigate these drugs in the perioperative setting.

So just to highlight what some of those trials are. The PROTEUS trial is a randomized, double-blinded, placebo-controlled, phase 3 trial that is looking at perioperative apalutamide in patients with high-risk localized or locally advanced prostate cancer where patients will receive 6 months of apalutamide and ADT prior to RP, followed by 6 months of apalutamide and ADT after RP. The primary endpoint there is path CR and MFS.

There are other neoadjuvant-based studies. The GUNS study is looking at a biomarker-based strategy in the neoadjuvant setting. The NePtune trial is looking at olaparib plus ADT and patients who are BRCA 1/2 mutated.

Additionally, there are adjuvant-based strategies. The ERADICATE trial is looking at darolutamide post RP for patients who are high risk and actually integrates the Decipher score and the CAPRA score in that trial enrollment. And the ADAM trial is looking at patients who have high-risk disease, post RP, randomizing to apalutamide and observation. So these are kind of surgical-based studies that are looking at therapy intensification for localized disease.

Neeraj, can you highlight some of the radiation studies that are currently ongoing?

**Dr. Agarwal:**

Of course. Actually, radiation therapy studies got started after the success of the STAMPEDE trial with abiraterone in the context of locally advanced, localized high-risk prostate cancer where patients had to have a locally large prostate gland, T3, T4, if they had lymph nodes enlargement or if they had high PSA level. .

And I think success of abiraterone in that setting has really been very encouraging. And that has led to initiation of two trials, at least large trials, large randomized controlled trial, in the context of radiation therapy with androgen receptor pathway inhibitor. And one of them is a DASL-HiCaP trial, which include patients with this localized high-risk prostate cancer who are starting radiation therapy. And a difference from previous trial is patients who are starting salvage radiation therapy after failure of prior radiation therapy are also allowed. And they are randomized to radiation therapy plus androgen deprivation therapy, plus/minus darolutamide for 2 years. Another trial in this setting is ENZARAD trial, very similar inclusion criteria where patients are randomized to radiation therapy, plus androgen deprivation therapy, plus/minus enzalutamide for, again, 2 years.

Metastasis-free survival is the primary endpoint for both these trials. And I'm really hoping that these trials will be successful that will allow our patients to have the opportunity to get a drug beyond abiraterone.

**Dr. McKay:**

That's exciting. It's really exciting to see all the novel drugs being developed. And appreciate you watching our program today. Thank you.

**Announcer:**

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