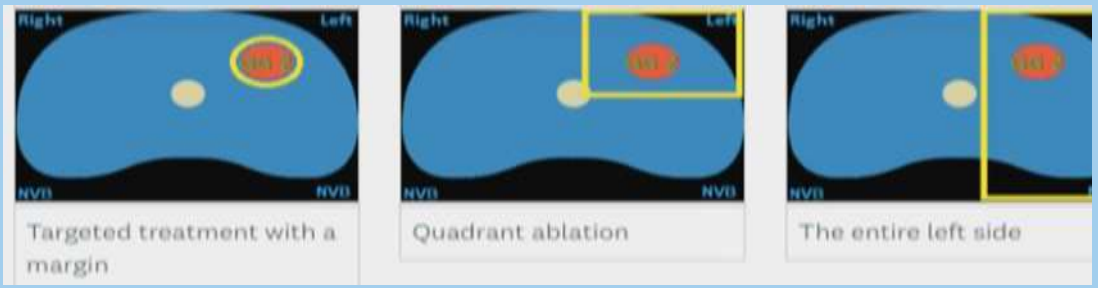
II. Focal Treatment Options:



Source: T. Polascik MD “Consensus Results” International Symposium on Focal Therapy & Imaging in Prostate & Kidney Cancer 2020

- “Focal” area: lesion (+ margin), quadrant, hemi-gland, other
- Energy sources: Ice, Laser, Ultrasound, Electricity, Gold Nanoparticles, etc.
- Clinical trials: eligibility, endpoints, biopsies, etc. are “apples and oranges”
- Who is a good candidate? See L Klotz MD “SUO-AUA Summer Webcast: Focal Therapy for Prostate Cancer Use and Misuse of FT”,

A. Cryo (Cryotherapy)

- Widely used for decades – mostly for salvage treatment
- Issues
  - Guidance is challenging
  - Ice ball is hard to control – not precision of newer focal treatments
  - Significant ED risk
- Covered by insurance

B. FLA (Focal Laser Ablation)

- Available on all size prostates
- Treats specific lesion(s) plus margin
- In-bore (optimal guidance) with thermal monitoring to prevent collateral damage
- May not be optimal for large lesions

C. HIFU (High Intensity Focused Ultrasound)

- May not be appropriate
  - Larger prostates (or may need TURP)
  - If calcium is present in the prostate
- Outpatient with MR “Fusion” guidance
- Often hemi-gland
- In-bore version (MRgFUS) has better oncologic outcomes in trials but has limited availability

D. TULSA-PRO® (Transurethral Ultrasound Ablation of the Prostate)

- Like HIFU
  - ➢Energy source is Ultrasound
  - ➢If calcium is present in the prostate, may not be a good option
- May not be effective if lesion is too close to urethra
- Not transrectal, so lower serious infection risk
- In-bore (optimal) guidance with thermometry
- Protocol is evolving: anesthesia/sedation, setting, type/duration of catheter; from whole gland to focal?

Insurance Hurdles: Cancer Treatment in US

1) Food & Drug Administration (FDA) ***allows it to be tried***
2) Rigorous, regulated trials show it is safe and effective over long term
3) FDA ***approves it for a specific "indication" such as low-risk prostate cancer***
4) National Comprehensive Cancer Network (NCCN hospital centers) and physician associations add it to their Guidelines for specific diagnoses and risk classes of patients
5) American Medical Association (AMA) sets up new procedure code(s)
6) Center for Medicare & Medicaid Services (CMS) sets fees by facility type, zip, etc.
7) Each carrier re-considers whether it is still "experimental" and sets fees

CMS and carriers will not reimburse without FDA cancer indication (Dr. Inderbir Gill, USC, International Symposium of Focal Treatment 2020); exception: CMS may grant temporary C-Code fees for outpatient facility

Summary: Select Focal Treatments

	FLA	HIFU	TULSA-PRO
Type of "Focal":	True = Lesion + Margin	Often Hemi-gland	TACT: Whole Gland; Focal studies scheduled
Source: "Int'l Symposium of Focal Treatment & Imaging in Prostate & Kidney Cancer" 2020:	Dr. J Feller : "Phase 2 MR-Guided Laser Focal Therapy: 10 Year Interim Results"	Dr. L Klotz: "Is AS After FT the Same as de Novo AS?"	
Oncologic outcomes - recurrence:	**CS: 23% in-field/4% outfield (improving with more margins)**	**EDAP, Ablatherm & Sonablate: 37% - 41%; MRgFUS (in-bore): 9%**	**CS: 21% + 14% Not CS (Whole Gland trial after 1 year)**
Other outcomes vary and are generally favorable:	Side Effects: good to excellent; PSA & Metastasis Free Survival: excellent; Long-term Outcomes: unknown		
Cost – varies by provider/services:	$25,000 + or -	$25,000 + or -	$22,000-$32,000 + or -
FDA status:	"Cleared" for soft tissue. But *no approval for prostate cancer*		

"Devil is in details": doctor's experience/outcomes, GS, setting, endpoints, lesion location/size, guidance, sedation/anesthesia, catheter, ADT, follow-up biopsy

III. Q & A

Thank you!