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SPARED – DATA COLLECTION

Core Data Elements

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Endpoints of Data Collection

- Standardized assessment aims to provide measurable impact of treatment
- Reliable data collection provides basis for predicting efficacy
- In a clinical trial format, data collection is well-defined and performed on pre-specified time points
- Registry data aims to provide reliable data to allow for treatment assessment
  - Follow up data over long time frame is possible
  - Follow up time points not standardized

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Pros/Cons of Registry Data

- Advantages
  - Wider inclusion and exclusion criteria
  - Potentially results in larger patient enrollment
  - May improve detection of less common results
  - Provides basis for assessing changes in treatment over time
  - Mirrors “real world” use
- Disadvantages –
  - Quality of data
  - Less closely monitored
  - Prone to confounders

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INDEX Trial – Phase II, Single Arm Trial

- Primary Endpoints -
  - Evaluate medium term oncologic output following HIFU (conversion to surgical management or XRT)
  - Provide data on long term cancer control (mets, mortality) following partial gland ablation
- Secondary Endpoints –
  - Quality of life outcomes (continence, potency)
  - Determine utilization and cost effectiveness
  - Disease control at 5 and 10 years
- Follow up protocol –
  - Post treatment PSA 3, 6, 9, 12, 18 and 24 months
  - MRI and prostate biopsy ~ 12 month after treatment

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SPARED Registry Delphi Process

Development of a Nationally Representative Coordinated Registry Network for Prostate Ablation Technologies

Patient Data

- Age
- Race
- Comorbidities
- Primary or salvage prior treatment
- Prostate volume
- Clinical stage
- Pretreatment biopsy results
- Pretreatment PSA
- Pretreatment Gleason score (ISUP Group)
- Number of cores obtained
- Number of positive cores
- Type of biopsy performed
- Pretreatment MRI results
- Baseline HRQOL scores

Patient reported outcomes:
Every patient:

- IPSS
- IIEF-5
- MSHQ-EjD

- Every 4th patient – EPIC – 26

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SPARED Registry Delphi Process

Development of a Nationally Representative Coordinated Registry Network for Prostate Ablation Technologies

Patient Characteristics	
Age	Pretreatment PSA
Race/ethnicity	Pretreatment biomarkers/genomic tests
Body mass index	Pretreatment clinical stage
Comorbidities:	Pretreatment biopsy information:
ASA physical status score	Type of biopsy performed
Specific comorbidities*	Pretreatment Gleason/ISUP
Baseline HRQOL scores:	Number of positive cores/total cores
IIEF-5	Maximum tumor core length
I-PSS	Pretreatment MRI information:
MSHQ-EjD	Number of lesions
EPIC-26	Location of lesions
Prior treatments†	PI-RADS score of lesion(s)
Pretreatment prostate volume	Volume of lesion
Prior transurethral resection or incision of prostate or bladder neck	

~ 20-24 data categories

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SPARED Registry Delphi Process ~ 8 data categories

Development of a Nationally Representative Coordinated Registry Network for Prostate Ablation Technologies

Treatment Data

- Type of device use (including Unique Device Identifier)
- Targeting imaging modality (US, MRI)
- 6 Distinct Patterns of ablation:
  - Whole Gland
  - Hockey Stick
  - Hemiablation
  - Quadrant
  - Multifocal
  - Focal (index lesion alone)
- Volume of ablation zone
- Treatment margin
- MRI PI RADS v2 segment location
- Ablation time
- Device malfunction or failure during treatment

Treatment Characteristics
Type of device used/UDI
Image guided ablation (ultrasound, MRI)
Volume of ablation zone
PI-RADS version 2 segment location(s)
Margin size
Ablation time
Pattern of ablation:
Whole gland
Hockey stick
Hemiablation
Quadrant
Multifocal (multiple index lesions)
Focal (index lesion alone)
Device malfunction or failure during treatment

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SPARED Registry Delphi Process ~ 10 data categories

Development of a Nationally Representative Coordinated Registry Network for Prostate Ablation Technologies

Outcomes Data - Oncologic

- Post Ablation Imaging
  - MRI at 12 months
  - Capture post ablation prostate volume
- Post ablation Prostate biopsy
  - 12 months
  - In field and out of field biopsy
  - Gleason grade
- Progression Free Survival (need for subsequent definitive treatment)
- Post Treatment PSA
- Biomarkers/Genomics

Oncologic Outcomes
Posttreatment PSA
Posttreatment biomarkers/genomic tests
Biochemical-free survival
Re-treatment free survival
Progression-free survival
Disease specific survival
Overall survival
Posttreatment biopsy information:
Indication for biopsy*
Method of biopsy
Timing of biopsy
Total number of in field/out of field cores obtained
In field positive biopsies
Out of field positive biopsies
In field clinically significant disease†
Out of field clinically significant disease†
Prostate cancer length
Posttreatment MRI information:
Indication for imaging*
Method of imaging
Timing of imaging
Results of imaging
Posttreatment prostate volume

SPARED Registry Delphi Process ~ 5 data categories

Development of a Nationally Representative Coordinated Registry Network for Prostate Ablation Technologies

Outcomes Data – Functional/Safety

- Record
  - Retention
  - UTI
  - Incontinence
  - Stricture
  - Osteomyelitis
  - Fistula
  - Resolution of complication
- Clavien-Dindo Classification score
- HRQOL using same tools as pre-treatment

Functional and Safety Outcomes
Posttreatment HRQOL: timing of administration and results:
IIEF-5
I-PSS
MSHQ-EjD
EPIC-26
Clavien-Dindo classification scale
Specific genitourinary complications:
Urinary retention
Urinary tract infection
Urethral stricture
Urinary incontinence
Osteomyelitis
Rectourethral fistula
Resolution/persistence of adverse events

HEAT Registry Experience

Collaborative effort to collect data from users employing Sonablate device

- Ongoing coordination and discussion of data tools and minimum data requirements

- Recognition of “Legacy” data
  - Data from patients treated from 11/2015 to present
  - May differ from data collected in a prospective fashion

- Prospective Data – to be handled differently – undergoing discussion now

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HEAT Registry Experience

Legacy Data:

- **Minimum Core Data**
  - Consensus that data includes:
  - Age
  - Race
  - Comorbidities
  - Primary or salvage prior treatment
  - Prostate volume
  - Clinical stage
  - Pretreatment biopsy results
  - Pretreatment PSA
  - Pretreatment Gleason score (ISUP Group)
  - Number of cores obtained
  - Number of positive cores
  - Type of biopsy performed
  - Pretreatment MRI results
  - Baseline HRQOL scores – IPSS/SHIM

Outcomes Data - Oncologic

- Post Ablation Imaging
  - MRI
- Post ablation PSA

- **Post ablation biopsy – Not required – record when available**

Outcomes Data – Functional/Safety

- Urinary retention/catheter time
- Complications
- HRQOL – IPSS/SHIM

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SPARED Registry

Core Data - or Minimum Data Entry Requirements

- Remain to be defined
- Any data is good data?
- Rules of reporting? –
- Tools/mechanism for ongoing data collection
- IRB/Data sharing agreements

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THANK YOU

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