Quality of Life and Your Cancer Patients: How Prostatic Artery Embolization Can Help.

Moffitt Clinical Grand Rounds
October 23, 2020

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Diagnostic Imaging & Interventional Radiology
Disclosures

• Grant support – Canon Medical
Objectives

- Identify and quantify lower urinary tract symptoms (LUTS) from benign prostatic hyperplasia (BPH) in your male patients
- Understand the role of prostate artery embolization (PAE) in the management of lower urinary tract symptoms from benign prostatic hyperplasia
- Know indications for prostate artery embolization in men with cancer outside of the prostate
Agenda

• Background
• What is prostatic artery embolization (PAE)?
• PAE and Your Patient – Indications, Size and Questions for them
• PAE and Your Patient – What to expect after the procedure
• PAE at Moffitt – Experience and Research
• PAE Sample Cases
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Benign Prostatic Hyperplasia

- **BPH**: Proliferation of smooth muscles and epithelial cells in the prostatic transition zone
  - Multi-factorial process, but testosterone and its analogues play central role
- **Autopsy proven prevalence**
  - ↑ starting at age 40-45
  - 60% @ 60 years old\(^1\)
  - 80% at 80 years old\(^1\)
- **Over half of all male Moffitt patients likely have some degree of BPH**

Benign Prostatic Hyperplasia

- Enlargement of the prostate may cause 
  symptomatic obstruction along the prostatic 
  urethra $\rightarrow$ “BENIGN PROSTATIC OBSTRUCTION” (BPO)
- Not all BPH results in symptoms
  - BPH that results in BPO creates Lower Urinary 
    Tract Symptoms (LUTS)
  - LUTS from BPH are the focus for our patients 
    because of detrimental effects on QoL

\[^2^\text{Berry SJ, Coffey DS, Walsh PC et al: The development of human benign prostatic hyperplasia with age. JUrol 1984;132:474.}\]
What are Lower Urinary Tract Symptoms (LUTS)

- Occur in males and females with similar frequency
- Result of many possible etiologies
- Lower Urinary Tract Symptoms (LUTS) consist of one or more of the following:
  - Urinary frequency
  - Urinary urgency
  - Urinary incontinence
  - Several other symptoms
- Moderate-severe LUTS ~50% in the 8th decade of life
  - 50% of your male Moffitt patients may be suffering from LUTS

What are Lower Urinary Tract Symptoms (LUTS)

- Add up points
- Categorize symptoms
- Simply way to quantify LUTS for your male patients
BPH and LUTS

• Histological BPH is common, and may lead to prostatic enlargement
• Not all BPH results in enlargement, and not all enlargement causes LUTS
  o More confusing: LUTS can occur without enlargement in some cases
• Acute urinary retention from BPH
  o 34.7 episodes per 1,000 patient years in men ≥ 70 yo with moderate-severe LUTS¹
• 90% of men 45-80 yo suffer some type of LUTS²
  o LUTS from BPH are VERY common in male Moffitt patients

²McVaryK: BPH: Epidemiology and Comorbidities. AmJManagCare 122006; 5 Suppl: S122
AUA Guidelines for Management of LUTS from BPH

- Goals of treatment:
  - Prevent complications associated with LUTS/BPH → ACUTE URINARY RETENTION
  - Alter BPH progression and associated co-morbidities → improve QoL

- 1st line therapy:
  - Lifestyle changes
  - Alpha-blockers (e.g. tamsulosin/Flomax)
  - 5-α reductase inhibitors* (e.g. dutasteride/Avodart)
  - PDE-5 inhibitors (e.g. sildenafil/Viagra)

- Medical therapies can have profound side effects for patients
  - Dizziness
  - Hypotension
  - Dry eyes
  - Decreased libido
  - Impotence

*Controversial effect on development of prostate cancer
AUA Guidelines for Management of LUTS from BPH

• Goals of treatment:
  o Prevent complications associated with LUTS/BPH \(\rightarrow\) ACUTE URINARY RETENTION
  o Alter BPH progression and associated co-morbidities \(\rightarrow\) improve QoL

• 2nd line therapy for refractory cases:
  o Surgical/Interventional Techniques
AUA Guidelines for Management of LUTS from BPH

- Intervention is dependent on size
  - > 60 grams is considered “Large”
- TURP is the gold standard for normal sized prostates
- Several treatment options exist

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**Surgical Therapy**

- **Assessment of Prostate Size**
  - Large Prostate
    - Simple Prostatectomy
    - HoLEP
    - ThuLEP
  - Average Prostate
    - HoLEP
    - PVP
    - PUL
    - ThuLEP
    - TUMT
    - TURP
  - Small Prostate
    - HoLEP
    - PVP
    - PUL
    - ThuLEP
    - TUMT
    - TURP

**Size Independent Options**

- Eligible patients who desire preservation of erectile and ejaculatory function may be offered PUL or water vapor thermal therapy as data indicate that both therapies provide a greater likelihood of preservation of sexual function.
Treatment Options for LUTS – TURP (Gold Standard)

- **Trans-Urethral Resection of the Prostate**
  - Outpatient procedure
  - Typically requires anesthesia/OR
  - Side effects:
    - Incontinence
    - Retrograde ejaculation
    - Urethral stricture
    - Bladder neck contracture
    - Erectile dysfunction
    - Gross hematuria/re-do
Treatment Options for LUTS – Laser Therapy

- Laser Therapy: Holmium Laser Enucleation (HoLEP) and Thulium (ThuLEP)
  - Size independent
  - Less concern for significant blood loss
  - Newer technique
  - Less data
• **Prostatic Urethral Lift ("UroLyft")**
  - No ideal for “large” glands, or for patients with median lobe physiology
  - Trans-prostatic suture implants pull/widen the lumen of the prostatic urethra towards the capsule
  - Mixed data, with possibly increased short-term side effects (eg dysuria, pelvic pain, bladder spasm)
Treatment Options for LUTS – Prostatectomy

- Simple Prostatectomy
  - Still gold standard for “large” glands
    - Good option for good surgical candidates, given robotic and laparoscopic approaches
    - Data limited on long term clinical outcomes
      - Urinary incontinence still a possibility
Treatment Options for LUTS – PAE

• Prostate Artery Embolization
  o Outpatient procedure
  o Does not require Foley Catheter
  o No risk of incontinence
  o Greatest risk is “not working”
  o Side effects
    • Urinary retention
    • UTI
    • Non-target embolization to the rectum, penis, bladder
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What is PAE?

- Angiographic technique using real time x-ray and contrast dye to identify pelvic arterial vasculature
  - Access the femoral or radial artery
  - Navigate catheters to bilateral internal iliac arteries
  - Navigate microcatheters to bilateral prostatic arteries
    - Restrict blood flow to the prostate utilizing 300-500 micron particles that lodge in prostatic capillaries
  - Ischemic necrosis results in relief of pressure around the prostatic urethra as well as prostate volume reduction
What is PAE?

• Outpatient procedure
• Performed in Interventional Radiology, 3rd floor MCB
• Moderate sedation (IV Versed and Fentanyl) used
  o Administered by IR RNs
  o Anesthesia not necessary (no propofol)
What is PAE? - Workflow
What is PAE? - Workflow
What is PAE? – Pre/Post-Op Care

Pre-Op
• LUTS evaluation
  o IPSS/AUA/IEEF questionnaire
  o Medical management trial
• Prostate CA r/o
  o PSA
  o Baseline MRI/CT
  o TRUS-bx if needed
• Enlarged prostate (> 80 gm?)

Post-Op
• f/u with IR @ 6 weeks, 12 weeks, 6 months, 12 months and annually
  o IPSS/QoL
  o PSA
  o MRI/CT
• f/u with GU surgery and/or rad onc if concomitant prostate CA
What is PAE? – Day of Procedure

Pre-Op
• Antibiotics
• Possible Foley catheter insertion
• Bloodwork
• 2 hour procedure time

Post-Op
• Foley catheter removed if not indwelling
• Cipro/Vesicare/Pyridium/Ibuprofen standing x 7 days
• Discharge home
What is PAE? – Clinical Outcomes

- Significant LUTS improvement
  - >90% of men will have significant LUTS improvement at 12 weeks
  - > 90% of men have persistent improvement at 2 years

- Significant QoL improvement
  - >90% of men will experience at least 1 category improvement at 12 weeks
What is PAE? – Volume Reduction

- 18-40% size decrease
  - US, CT or (ideally) MRI
    - AP x TR x CC dimensions x 0.52
  - ↑ gland size, greater the % volume reduction
- Preferential central gland reduction
  - Sparing of the neurovascular bundle
- Max volume reduction at 12 weeks post PAE
What is PAE? – Side Effects & Complications

• **Side effects** may occur in up to 50% of men - expected
  o Self limited and resolve by 2^nd^ week
    • Acute Urinary Retention
    • Recurrent UTI
    • Moderate dysuria/bladder spasms

• **Complications** occur in < 1% of cases, and are a result of non-target embolization of shared pelvic vessels - unexpected
  o Focal bladder necrosis → prolonged dysuria
  o Focal rectal necrosis → hematochezia
  o Focal meatal/penile necrosis
  o Conservative therapy and resolution at 4-6 weeks
What is PAE? – Side Effects & Complications

A Systematic Review of Prostatic Artery Embolization in the Treatment of Symptomatic Benign Prostatic Hyperplasia

Michelle Kuang¹ · Anthony Vu¹ · Sridharma Athreya²,³

<table>
<thead>
<tr>
<th>Complication</th>
<th>Number of patients</th>
<th>Incidence (%)</th>
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</thead>
<tbody>
<tr>
<td>Major complications</td>
<td></td>
<td></td>
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<tr>
<td>Vesicular artery dissection</td>
<td>1</td>
<td>0.13</td>
</tr>
<tr>
<td>Persistent UTI requiring hospitalization</td>
<td>1</td>
<td>0.13</td>
</tr>
<tr>
<td>Focal bladder wall ischemia</td>
<td>1</td>
<td>0.13</td>
</tr>
<tr>
<td>Minor complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute urinary retention</td>
<td>60</td>
<td>7.61</td>
</tr>
<tr>
<td>Rectal bleeding</td>
<td>45</td>
<td>5.71</td>
</tr>
<tr>
<td>Hematospermia</td>
<td>40</td>
<td>5.08</td>
</tr>
<tr>
<td>Hematuria</td>
<td>39</td>
<td>4.95</td>
</tr>
<tr>
<td>Dysuria</td>
<td>36</td>
<td>4.57</td>
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<tr>
<td>Urinary tract infection</td>
<td>34</td>
<td>4.30</td>
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<td>Irritative voiding</td>
<td>28</td>
<td>3.55</td>
</tr>
<tr>
<td>Inguinal hematoma</td>
<td>16</td>
<td>2.03</td>
</tr>
<tr>
<td>Balanoposthitis</td>
<td>6</td>
<td>0.76</td>
</tr>
<tr>
<td>Post-embolization syndrome</td>
<td>6</td>
<td>0.76</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4</td>
<td>0.51</td>
</tr>
</tbody>
</table>

2.5%  1.5%  3.4%  4.2%  4.9%
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PAE and Your Patient – Indications

Chronic Urinary Retention
- Men who are Foley catheter dependent with longstanding BPH
- Men who are straight catheterizing with longstanding BPH

Acute Urinary Retention
- Men who are in ACUTE URINARY RETENTION DUE TO BPH/BPO
- Men who are in ACUTE URINARY RETENTION DUE TO PERSISTENT HEMATURIA
  - If hematuria is related to the prostate
Inability to tolerate anesthesia, chemotherapy or radiation due to LUTS
  o If LUTS from BPH are affecting cancer therapy, PAE should be considered
  o Common for men to “tip over” into urinary retention from anesthesia medications
    • If this happens inpatient, PLACE FOLEY CATHETER AND CALL GU/IR
    • Do NOT recommend intermittent catheterization prior to evaluation by GU and IR for possible PAE
Men with moderate-severe LUTS from BPH with OUT prostate cancer
  - Refractory to medical therapy
  - Chronic LUTS (several year history)
    - Daily life and Quality of Life are significantly affected
  - **ASK QUESTIONS ABOUT URINARY HABITS AND SLEEPING HABITS**
    - IPSS or AUA
PAE and Your Patient – Indications

LUTS with↑ PSA without prostate cancer
  o **GU consult** to evaluate for PCa
    • PSA
    • MRI
  o Once PCa has been ruled out, consider PAE for BPH
    • ↑ PSA can often result from BPH alone
    • PSA significantly decreases after PAE
      • PSA velocity is a more important metric
Chronic Prostatitis/Chronic Pelvic Pain Syndrome

- Under diagnosed condition in men
  - Chronic pelvic pain after inciting event (e.g. trauma, radiation)
  - Bacterial prostatitis should be ruled out
  - LUTS is a component, but PAIN is the differentiator
- PAE has been shown to be effective for medically refractory cases (~50%)
PAE and Your Patient – Indications

- Intractable hematuria from prostatic hemorrhage (aka “hemorrhagic prostatitis”)
  - Infection
  - Tumor
  - Trauma
  - GU and IR consult to evaluate for candidacy for PAE
PAE and Your Patient – Indications

- Men with PCa and LUTS
  - PRIOR to definitive radiotherapy
    - At least 6 weeks prior
  - Obstructive, locally advanced PCa
  - POST definitive radiotherapy with chronic GU toxicity/prostatitis
- These patients should be seen in conjunction with GU and radiation oncology
**PAE and Your Patient – Size**

- “LARGE” means > 60-80 grams
  - < 60, several options
  - LARGE prostates may respond more favorably to PAE
- Size can be measured on
  - US (eg. TRUS biopsy)
  - MRI
  - CT
  - PET/CT
• Do you have trouble with urination?
• Do you wake up at night to urinate?
• Are you on medications for an enlarged prostate?
  o Flomax (tamsulosin)
  o Cardura (doxazosin)
  o Avodart (dutasteride)
  o Proscar (finasteride)
• Have you been told that you have an enlarged prostate?
• Do you have a history of prostate cancer?
• Do your urinary symptoms affect your quality of or daily life?
PAE and Your Patient – What questions to ask your patients?

**International Prostate Symptom Score (I-PSS)**

<table>
<thead>
<tr>
<th>In the past month:</th>
<th>Not at All</th>
<th>Less than 1 in 5 times</th>
<th>Less than Half the Time</th>
<th>About Half the Time</th>
<th>More than Half the Time</th>
<th>Almost Always?</th>
<th>Your score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Incomplete Emptying</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>How often have you had the sensation of not emptying your bladder?</td>
<td></td>
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<tr>
<td>2. Frequency</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
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<tr>
<td>How often have you had to urinate less than every two hours?</td>
<td></td>
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<tr>
<td>3. Intermittency</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>How often have you found you stopped and started again several times when you urinated?</td>
<td></td>
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<td></td>
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<td>4. Urgency</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
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<tr>
<td>How often have you found it difficult to postpone urination?</td>
<td></td>
<td></td>
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<td>5. Weak Stream</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>How often have you had a weak urinary stream?</td>
<td></td>
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<td></td>
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<tr>
<td>6. Straining</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
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<tr>
<td>How often have you had to strain to start urination?</td>
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<td></td>
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<tr>
<td>7. Nocturia</td>
<td>None</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
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<tr>
<td>How many times did you typically get up at night to urinate?</td>
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</tbody>
</table>

**Quality of Life Due to Urinary Symptoms**

<table>
<thead>
<tr>
<th>Delighted</th>
<th>pleasantly satisfied</th>
<th>Mostly satisfied</th>
<th>Mixed</th>
<th>Mostly dissatisfied</th>
<th>Unknown</th>
<th>Terrible</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?

Score: 1-7: Mild 8-19: Moderate 20-35: Severe
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POD 0-7

• POD 0-1
  o Exacerbation of LUTS in up to 50% of men, to varying degrees
    • Dysuria
    • Bladder spasms
    • Burning
  o Prophylactic medications given for 7 days

• POD 2-7
  o Resolution of above symptoms
After POD 7 – 12 weeks

- By 1 week most men feel “changes” in the pelvic area
  - LUTS start to improve by 3 weeks
- Expect significant improvement at 6 weeks
- From 6-12 weeks, improvement may not be as striking
Beyond 12 weeks after procedure

- Most likely no significant further improvement
- Urinary Medications can be weaned after 12 weeks
- “Durability” of PAE is ~90% at 2-4 years
  - Repeat PAE is possible and works best for patients who demonstrated initial improvement but relapsed
- Patient follow up in IR clinic annually

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Volume reduction

- More “even” distribution of volume reduction compared to symptoms
  - At 12 weeks, expect ~20-40% reduction in size of prostate
  - Predominant findings are in the transition zone
- NO SIGNIFICANT EFFECT ON PROSTATE CANCER ITSELF
PAE and Your Patient – What to expect after the procedure

Catheterization

- **If the patient is in acute urinary retention before PAE - LEAVE THE FOLEY CATHETER IN PLACE**

- Foley catheter dependent patients
  - 1st voiding trial at 4-6 weeks
  - 2nd voiding trial at 12 weeks if first one fails
  - > 90% of the time, men will successfully be taken off the Foley after PAE

- Intermittent straight catheterization
  - We ask patients to wean catheterization based on output logs
  - ~75% of men will be able to come completely off straight catheters after PAE
Erectile function

- Data suggests no impact (positive or negative) on erectile function
- If function is normal before PAE, it will be normal after
- PDE-5 medications can and should be continued after PAE
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PAE at Moffitt

- Program started in 2017
- 92 cases to date
- 32 required “catheter”
  - 29 were able to have catheter out
- 2 cases of AUR post PAE (resolved by 2 weeks)
- 1 case of meatal necrosis post PAE (resolved at 4 weeks)

LUTS obstructive PCa  7
  - 2 Foley Dependent
  - 2 CIC Dependent
  - 2 SP Cath Dependent

LUTS localized non-obstructive PCa  34
  - 3 Foley Dependent
  - 2 CIC Dependent

LUTS BPH  35
  - 16 Foley Dependent
  - 1 CIC Dependent

Radiation/hemorrhagic prostatitis  16
  - 1 Foley Dependent
  - 3 CIC Dependent

Total PAE  92

CIC – Clean Intermittent Catheterization
SP – Supra-Pubic
• **MCC 20832**: “A Phase II Study to Evaluate the Safety and Efficacy of Prostatic Artery Embolization in Patients with Benign Prostatic Hyperplasia and Lower Urinary Tract Symptoms in the Setting of Localized Prostate Carcinoma”
  - SRC Approved
  - Pending IRB and Feasibility Approval
  - Expected date to be open for enrollment: January 2021
PAE at Moffitt – Research Studies for PAE

• Future studies:
  o PAE compared to ADT for volume reduction prior to RT
  o PAE for management of chronic prostatitis
  o Acute and chronic GU toxicity in patients who receive definitive radiotherapy for PCa and PAE for LUTS
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47 year old man with Gleason 6 prostate CA, BPH and severe LUTS:

- First attempt at PAE – pre-op labs:
  - Cr 22.4, K⁺ 8.5, peaked T waves on EKG → needed indwelling Foley and ICU stay for 3 days
- PAE performed 2 weeks later
- Foley catheter removed 6 weeks after PAE
73 year old man with H&N SCCA and inability to tolerate chemo-radiation due to BPH and severe LUTS with acute urinary retention requiring Foley placement:

- Successfully completed chemorads 1 week after PAE
- Foley catheter removed 6 weeks after PAE
- NED 3 years after diagnosis; no recurrence of LUTS 2.5 years after PAE
62 year old man with left renal mass and urinary difficulty after anesthesia required for appendectomy, also with persistently ↑PSA (~4.0) and negative prostate biopsies:

• PAE performed 6 weeks prior to ablative therapy for left renal mass requiring anesthesia
• Able to tolerate anesthesia without urinary retention
Summary

- Likely that > 50% of male Moffitt patients have moderate-severe LUTS
  - Most feared complication is urinary retention requiring Foley or straight catheterization
  - LUTS have a significant effect on QoL and patients’ ability to receive cancer therapy
- PAE is a novel, minimally invasive therapy for the management of LUTS in men with BPH
- Indications include:
  - Longstanding BPH and LUTS requiring medications or catheters
  - Inability to tolerate cancer therapy due to QoL decrease from LUTS
  - Pelvic pain and hematuria from arising from the prostate
Special Thanks

- GU Surgery: Drs. Powsang, Spiess, Gilbert, Sexton, Poch, Manley, Li
  - GU Oncology APPs and nurses
- GU Rad Onc: Drs. Yamoah, Johnstone, Grass, Torres-Roca, Montejo
  - GU Radiation Oncology APPs and nurses
- Dr. Gatenby, Dr. Letson, Dr. Harrison
- IR physicians, APPs, nurses and technologists
Moffitt's Physician Liaisons serve as a connection between Moffitt and the referring provider. Our team visit practices in Tampa and communities around central Florida.

We can provide:

- Communication with Moffitt Faculty and staff
- Information about new treatments and technologies
- Clinical Trial Updates
- Online referral support
- Access to medical records
- Continuing Medical Education programs
- Moffitt Faculty Tours
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- Continuing medical education programs
- Moffitt facility tours
- If you're a healthcare provider or part of a medical office and would like to know more about what a Physician Liaison can do for you, reach out to us.
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Questions?

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