

*The **AACC** CPOCT Division Presents*

***Promoting a Culture of  
Quality and Consistency in  
Critical and Point-of-Care Testing***

***24th International Symposium October 4-6, 2012  
Hilton Prague Hotel Prague, The Czech Republic***

This activity has not been approved for category 1 CME credit because the conflict indicated by the speaker could not be resolved according to guidelines from the Accreditation Council for Continuing Medical Education.

**AACC**



# Use of PTH at Point of Surgery for Non-Localized Cases of Hyperparathyroidism

Keck Hospital  
of USC

# Keck Hospital of USC

- Private, non-profit 400 bed hospital
- Teaching and research, USC Keck School of Medicine
- Approx. 40 parathyroid surgeries per year



# Hyperparathyroidism: Facts

- Hyperparathyroidism (HPT) is a disease of “stones, bones and abdominal groans”
- 100,000 new cases of HPT each year in U.S.<sup>1</sup>
- Annual parathyroidectomy cost of \$282 million<sup>2</sup>
- More common in women than men, increase with age in both sexes

<sup>1</sup>Melton LJ 3<sup>rd</sup>, J Bone Miner Res. 2002 Nov; 17 Suppl2: N12-7

<sup>2</sup>Right Diagnosis. Com

# HPT, Facts.....

- 85-88% of cases present single benign parathyroid adenoma
- ~11% result from diffuse hyperplasia of all parathyroid glands
- 1-5% of cases caused by multiple adenomas<sup>1</sup>
- Other challenges: ectopic gland location & supernumerary glands
- Hyperplastic or adenomatous tissue? Hard to tell even with frozen sections!

<sup>1</sup>American Academy of Otolaryngology-Head and Neck Surgery Foundation 2011

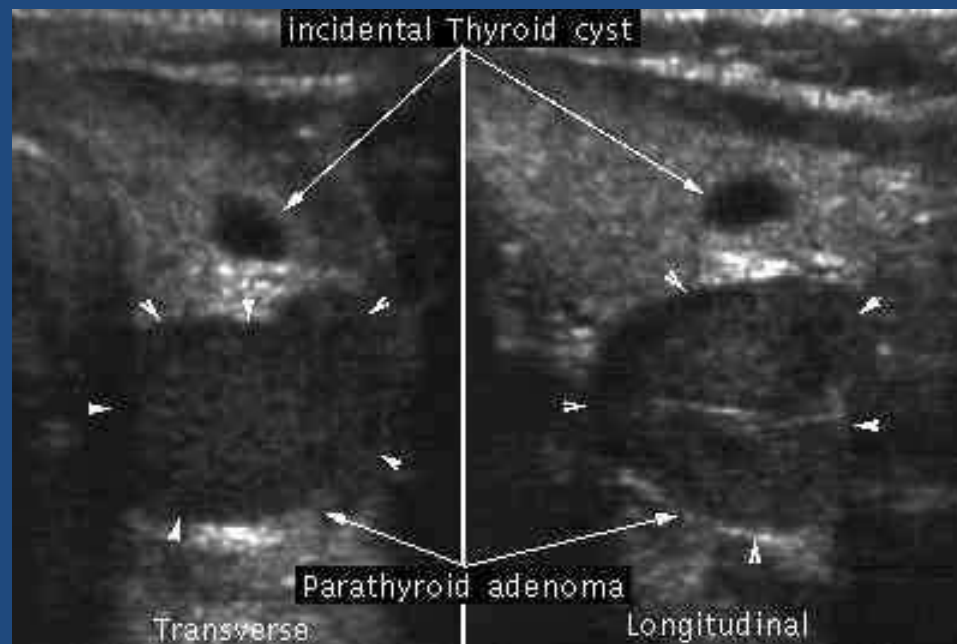
# HPT Diagnosis

- Diagnosis starts w/ elevated serum + 24-hour urine calcium
- Elevated intact chain PTH Levels
- Imaging studies: ultrasonography, sestamibi scintigraphy, MRI and gamma probe
- Is minimally invasive parathyroidectomy an option?
- Bilateral neck dissection: an option or a requirement?
- Of 320 labs surveyed in 2002, 92 performed intraoperative PTH's<sup>1</sup>

<sup>1</sup>Arch Pathol Lab Med. 2002 Sep; 126(9):1045-9.

# Pre-Op Imaging Studies

## Ultrasound Localization





# Pre-Op Imaging Studies

## Sestamibi Scans

- 80-90 % positive adenoma localization





# Sestamibi Scan: Predictive Value

**427 Patients with Hyperparathyroidism**

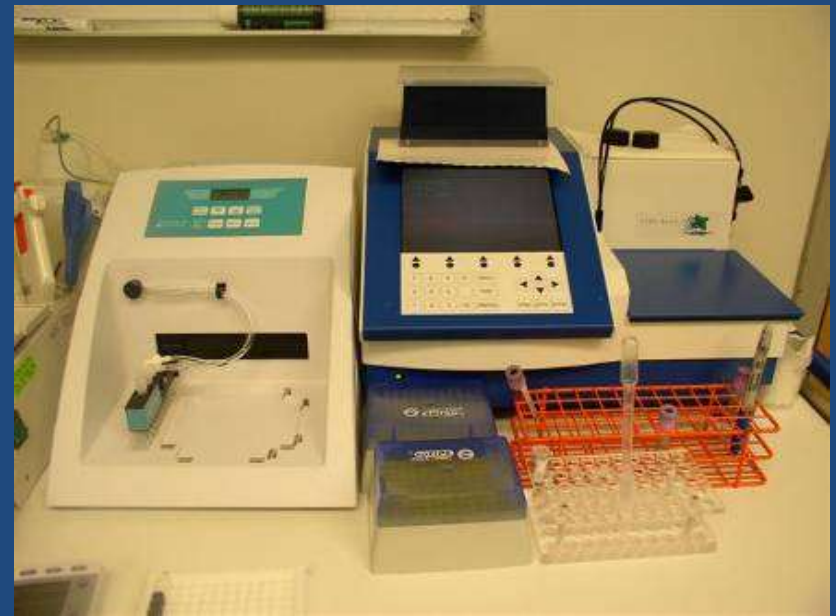
Positive Scan (240)	56%
Equivocal Scan (105)	25%
Negative Scan (82)	19%

# Operative Technique, Parathyroid Gland Surgery

- Experience counts
- Minimally invasive surgery
  - The proper candidate
  - Positive sestamibi scan/ and Ultrasound
  - Can be done under local if necessary
- Need for a 4 gland exploration

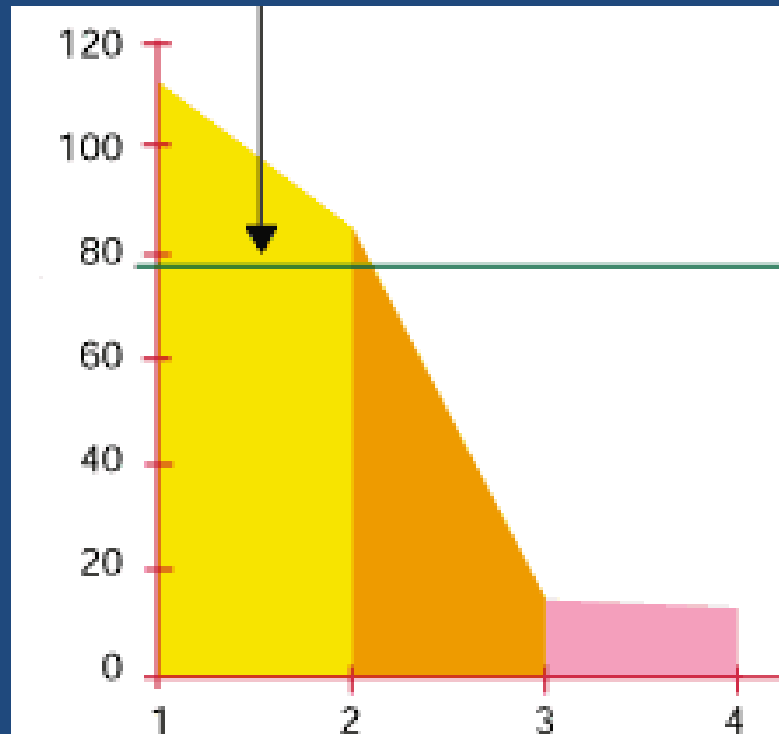
# Intraoperative PTH Monitoring at Point of Surgery

- PTH  $\frac{1}{2}$  life about 5 minutes
- Can obtain an immunoassay in 10 minutes
- Future Diagnostics, STAT IO-IPATH, Netherlands
- Immunochemiluminescence Methodology
- <http://www.future-diagnostics.nl/>



# PTH Concentrations Post Gland Removal

PTH in pg/ml



Time in minutes after gland removal

# Positive Pre-op Localization

- Peripheral serum PTH
- Open neck
- Remove adenoma
- Confirm cure 10-15 minutes after tumor removed
- Good candidate for minimally invasive, video-assisted approach

# Negative Pre-op Localization

- All imaging studies negative
- What options available?
  - Elective 4 gland exploration
  - Use Intraoperative PTH central vein (or intra-jugular vein) sampling

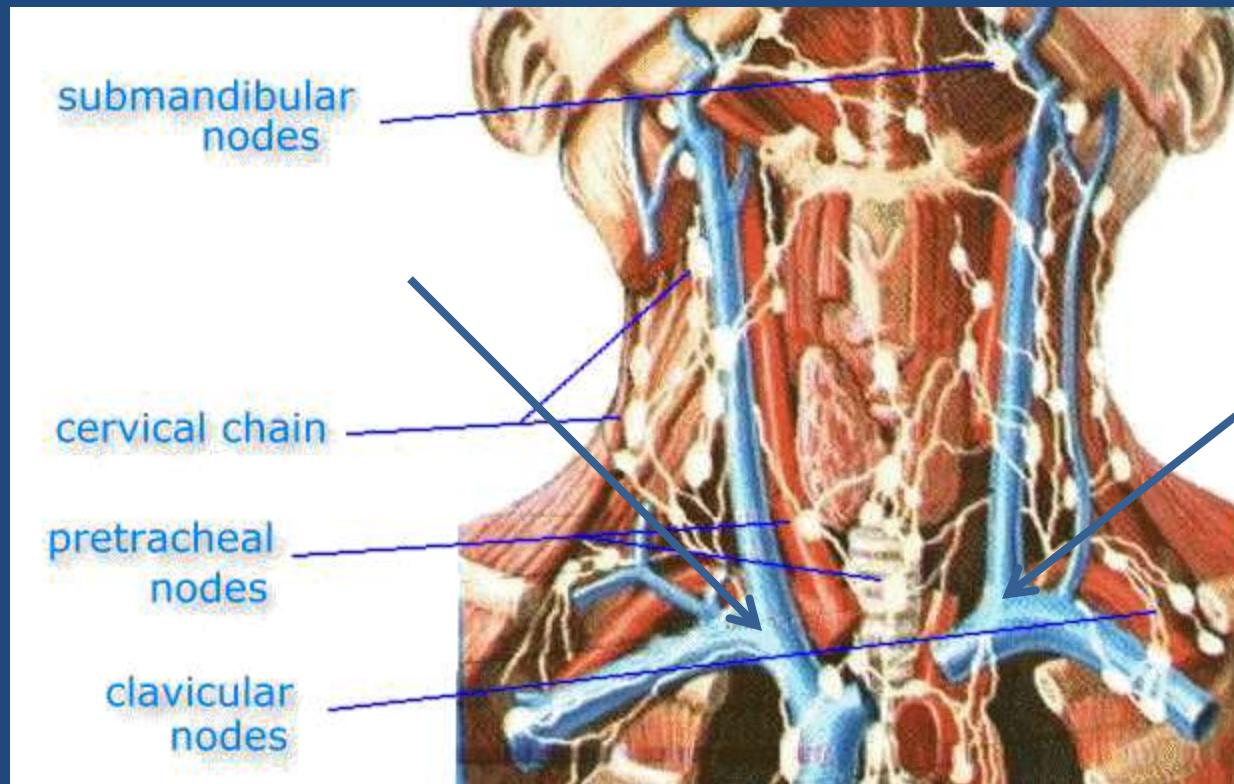


# Algorithm for Non-localization

- Use baseline intra-operative PTH split samples from the internal jugular (IJ) veins
- Split IJ samples can direct surgical exploration based upon the IOPTH gradient between the 2 sides ( $>20\text{pg/ml}$ )
- Blood must be obtained from the internal jugular veins low in the neck, before manipulation of the glands

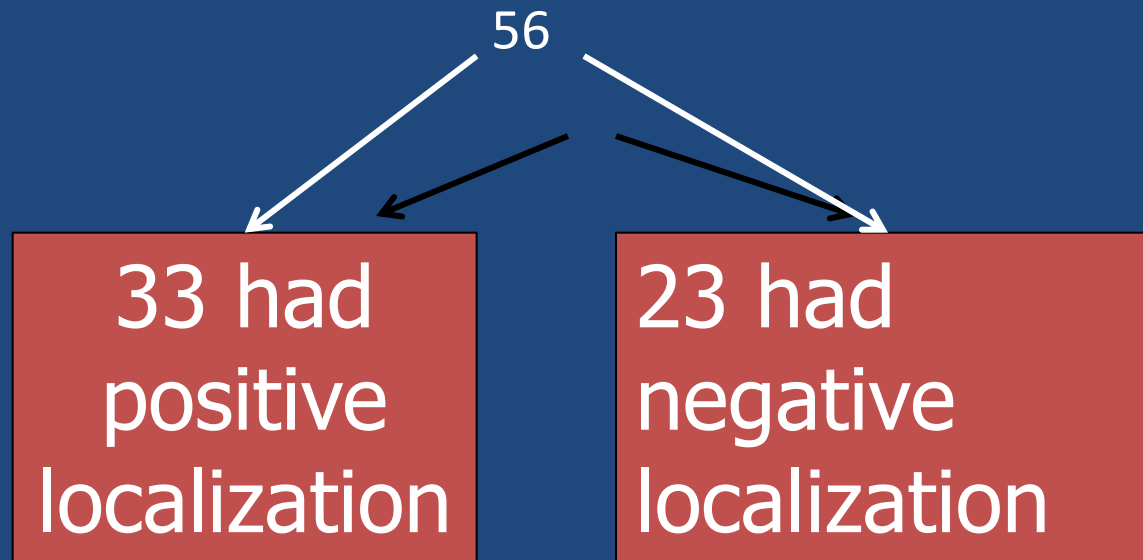
# Internal Jugular Vein Samples

Samples Taken Low in the Neck



# PTH IJ Gradient Study Population

- 66 patients with split IJ samples (2005-2010)
- 10 cases were secondary hyperparathyroidism



- There were 2 negative explorations in each group
- 52 cases were ultimately analyzed

# Site of Pathology

Site of Adenoma	Number
Left	23
Right	23
Hyperplasia	6

# PTH Gradient Results

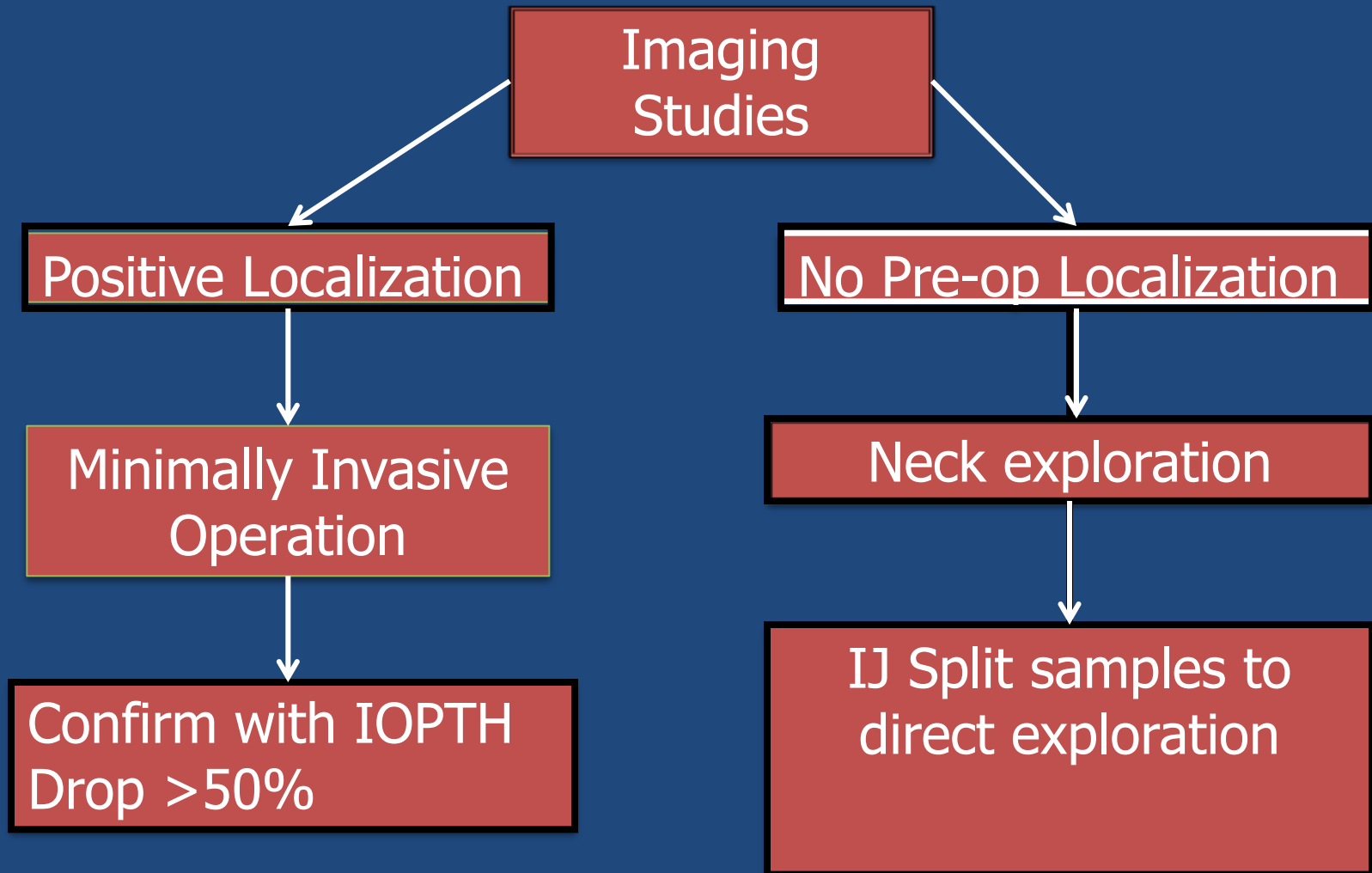
Site of Adenoma	RIJ Mean	LIJ Mean	<i>P</i> -value
Left 23	156	561	<0.001
Right 23	609	154	<0.004
Hyperplasia 6	158	133	0.43
<i>P</i> -value Left v. Right	<0.005	<0.003	

# Results

- The greater the absolute value of the gradient between the right and left IJ samples, the more likely the gradient was to predict the side of the tumor
- A gradient of  $>200$  was associated with a 100% accuracy of adenoma localization
- A gradient of 20-200 was associated with an 88% accuracy (15/17)



# Surgery for Hyperparathyroidism: Suggested Algorithm



# Intra-Operative PTH Testing

- Done in lab or at POS? A matter of time.
- Operating room turnover, billed @ \$94 per minute!
- If test done POS, save 15-30 minutes
- Cost/test difference: \$37.50 POS vs. \$3.61 in central lab
- Technologist has improved job satisfaction w/ POS/POCT

# IO-PTH: Summary

- Enhance patient outcomes by decreasing morbidity, mortality & hospital LOS<sup>1</sup>
- Short half life of PTH (~5 minutes) & suppressed secretion of PTH in normal glands after excision make IO-PTH useful
- Exclusion of hyperplasia is challenging in minimally invasive video-assisted procedures
- Increased success rate of surgery promotes culture of quality & consistency in patient care @ bedside

<sup>1</sup>Vikram Reddy, MD, Adil I. Khan, PhD, Alan T. Remaley, MD, PhD, Frank H. Wians, Jr, PhD, LabMedicine, Volume 37, Number 12, December 2006

# Is IO-IPATH Considered Lean<sup>1</sup>?

- Paperless ✓
- Quicker results ✓
- Pre-analytical, processing time eliminated ✓
- Less biohazard waste ✓
- Lower specimen volume, blood conservation ✓
- Lower medical errors ✓
- Enable integration of testing into clinical flow & clinical judgment ✓
- Improve clinical outcomes ✓

<sup>1</sup>Dr. Jay B. Jones, PhD, DABCC, Geisinger Health Systems: Process Improvement for Critical & Point of Care Testing, a Lean Perspective, 13 October, 2011.

