

Starting an INTRABEAM[®] Program in an Academic Setting

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Lessons From Two Programs

- **Northwestern - around 2010**
 - We were looking for a new Accelerated Partial Breast Irradiation (APBI) solution.
 - We believed there was a place for APBI
 - Using, on and off trial, single channel Mammosite and external beam APBI
 - Unhappy with the cosmetic outcomes
 - Started an Ad Hoc committee to look at all the options with formal presentations.
 - Led my Rad Onc
 - Engaged Surg and Med Onc

Factors in the decision for Intrabeam

- First and foremost was the data that was published in Lancet in 2010.
 - Would not have proceeded if we didn't think this was the absolute right thing for the patient!
- Nearly as important was the academic and differentiating possibilities.
 - First center in Chicago
 - Unique research opportunities
 - Differentiator

Development of the IORT “team”

- A Brachytherapy coordinator
- Previously, 4 breast surgeons and 3 radiation oncologists participating.
- Multiple physicists are also involved.

- 1st case- 1/10/11
- When I left: No recurrences – one patient treated as a boost developed an atypical pneumonitis.

Practical Aspects (my perspective)

- I saw the patient in consultation often “fitting in” by working backwards from a possible surgical date.
- If the patient agrees – I consent and state I will see the patient in the OR.
- The case is scheduled during my blocked IORT time.
- I arrive when it is time to place the device.
- The surgeon and I ultrasound to confirm placement.
- I deliver the radiotherapy and stay with the patient.

Outcome – First Experience

- Developed as a team looking at patient, academic and “differentiating” factors.
- Overall a success – we did receive significant local differentiation including media reports.

Second Experience

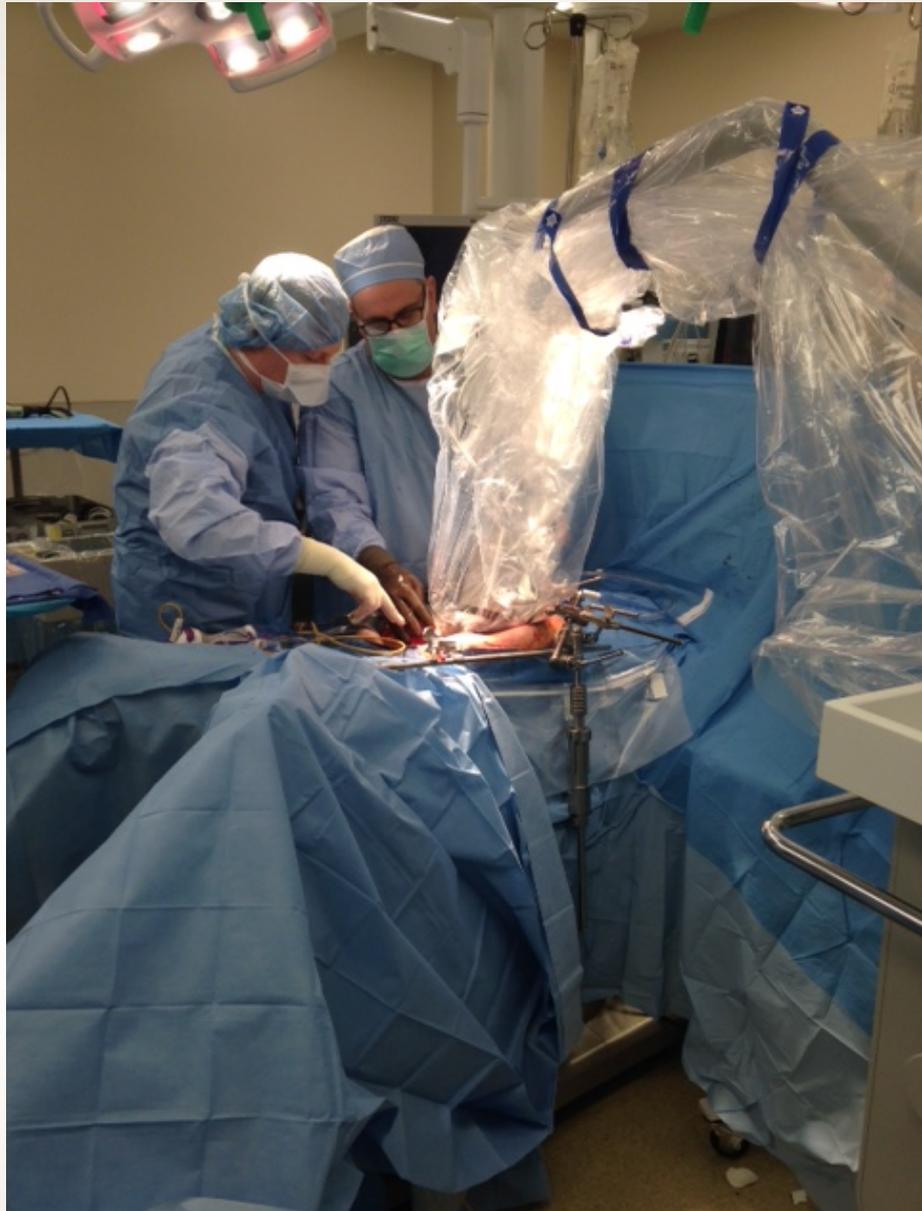
- Was recruited to Chair Loyola – across town and a competitor.
- Negotiated an Intrabeam device as part of the Chair package.
- Did not engage my new colleagues in the process and was meet initially with some “resistance”.

On The Other Hand

- At the time we purchased the new machine at Loyola the new flat and surface applicators became available
- Immediately began the process of initiating multiple investigator initiated trials – funded by my discretionary funds.
- Re-engaged the breast team and started the process to bring TARGIT-US to the institution.

Outreach

- Used our referral pattern of large salvage surgeries to promote our ability to do IORT for sites where traditional IORT is considered.
- First patient treated – referred to us before we had the machine to deliver IORT for a recurrent rectal cancer.



Development of a True Program

- Engaged my staff to develop innovative clinical programs and trials to bring this unique therapy to patients that may truly benefit from the therapy.
 - TARGIT-US Breast
 - Head and Neck
 - Pancreas
 - Spine
 - Colo-rectal
 - Gyn
 - Translational Research

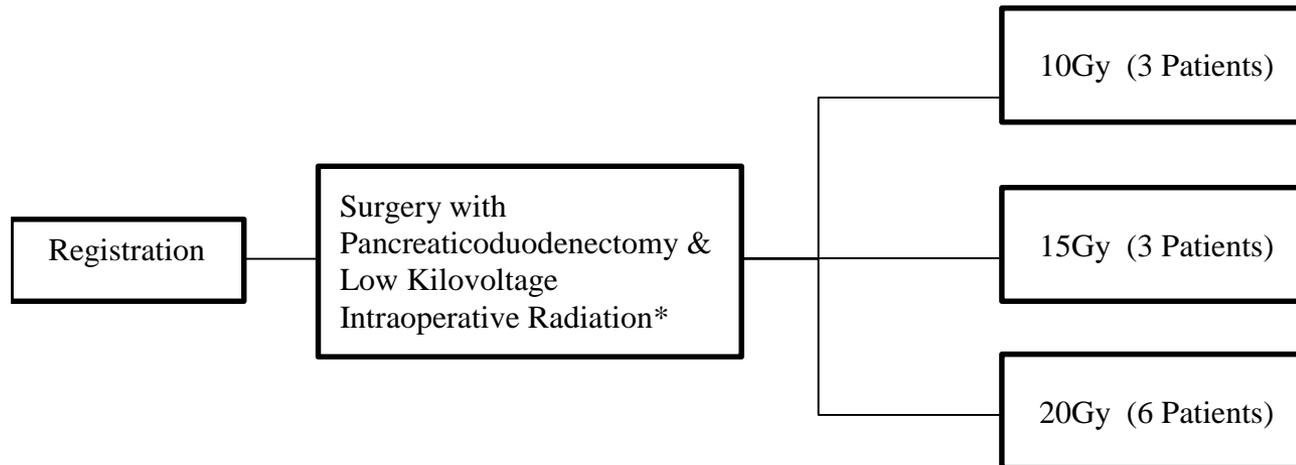
Head and Neck

- We have treated a number of head and neck cancer patient's.
- Dr. Emami will be discussing later in the session.



Phase I Study of Low KV IORT for Resectable Pancreas Cancer : PI Tarita Thomas, MD

Study Schema



* Dose prescribed to the surface of tumor bed



Background

- In 2013, an estimated 45,200 new cases of pancreatic cancer were diagnosed and 38,640 deaths resulted from this disease
- The standard of care for resectable pancreatic cancer is pancreaticoduodenectomy.
- Only 10-15% of patients are considered resectable at the time of diagnosis.
 - Of those who qualify, with surgical resection alone 5 year overall survival is 5-10%.
 - Only 20% will survive 5 years following the procedure with adjuvant chemotherapy and external radiotherapy due to local progression of the cancer and distant metastases.
- These poor overall survival rates underscore the need to identify new treatment approaches.



Background

- The margin status is an important predictor of surgical outcome for pancreatic cancer with the most common positive margins being the superior mesenteric artery (SMA) margin and posterior margin.
- This occurs 10-35% of the time due to surgical technical limitations.
- If the surgery results in a positive margin the median survival is 8-11 months. Common areas of local recurrence include the right lateral aspect of the SMA and the retroperitoneum.
- The purpose of this study is to determine safety of low kilovoltage radiotherapy delivery of a focused dose of radiation to the areas of concern for locoregional recurrence following pancreaticoduodenectomy.



Objectives

- Primary objective:
- To determine the dose limiting toxicity and maximum tolerated dose with low kilovoltage intraoperative radiation
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- Secondary objectives:
- To develop acute and chronic clinical toxicity profiles for this treatment modality
- To determine clinical disease outcomes



Inclusion Criteria

- Pathologically confirmed pancreatic adenocarcinoma.
- Age \geq 18 years.
- Performance status ECOG 0-1.
- Patient must have resectable disease. In order to be resectable the following criteria must be met:
 - Absence of distant metastases.
 - Clear fat planes around the celiac axis, hepatic artery, and superior mesenteric artery .
 - Absence of direct involvement of inferior vena cava or aorta.
 - If superior mesenteric vein (SMV) or SMV-portal vein confluence occlusion the portion must be deemed reconstructable by the surgeon.
- Complete history and physical examination including weight and ECOG performance status within 31 days of entry.
- Laboratory data obtained \leq 14 days prior to registration on study, with adequate bone marrow and organ function

First Patient on Pancreas Trial

- Unbelievably great outcome!

Kyphoplasty and Intrabeam

- Developed a phase 1 trial to confirm can be done safe.
- <https://youtu.be/nfveiSd0bUY>

Conclusion

- INTRABEAM offers unique opportunities in an academic center.
- Multi-disciplinary involvement is critical.
- Has been a true academic success for our program.

Questions

The 2016 U.S. INTRABEAM® User Meeting has been sponsored by ZEISS.

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