First Report of the Permanently Implantable Uni-Directional Planar LDR Brachytherapy for Patients with Locally Advanced Pancreatic Cancer

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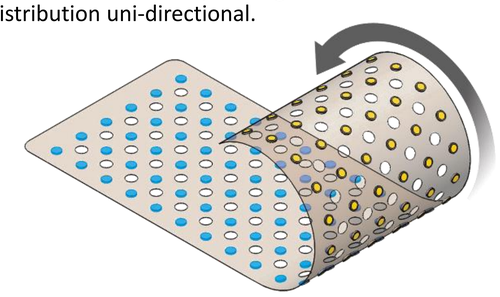
PURPOSE

- Surgery remains the only curative option for patients with pancreatic cancer, but there is a risk of 18%-40% of margin-positive resections reported in the literature which conveys high risks of local control and poor survival.
- Even with neoadjuvant therapy there is a risk of margin-positive resection given the proximity to major vasculature.
- This is the first report demonstrating the feasibility and tolerance of this novel, uni-directional ^{103}palladium (Pd-103) sheet which is implanted at the time of pancreatectomy for patients with close or positive margins.

MATERIALS & METHODS

- Prior to opening the Phase I/II CivaTech Study, 5 pts with concern for positive margins were treated with the implantable LDR sheet at the time of surgery.
- One of the pts had surgery and sheet placement as initial therapy. The other 4 received chemotherapy, chemoradiation followed by surgery and sheet placement.
- CivaSheet® is an FDA-cleared product consisting of a matrix of Pd-103 radiation sources on a bio-absorbable membrane with a gold shield that attenuates dose on one side of the device, making the radiation distribution uni-directional.



- Dose is prescribed to 5mm depth and in this study was between 38-45Gy EQD2.
- Outcomes evaluated included procedural time, time to implant the device, procedural complications related to sheet placement, length of hospital stay, and post-operative complications.

RESULTS

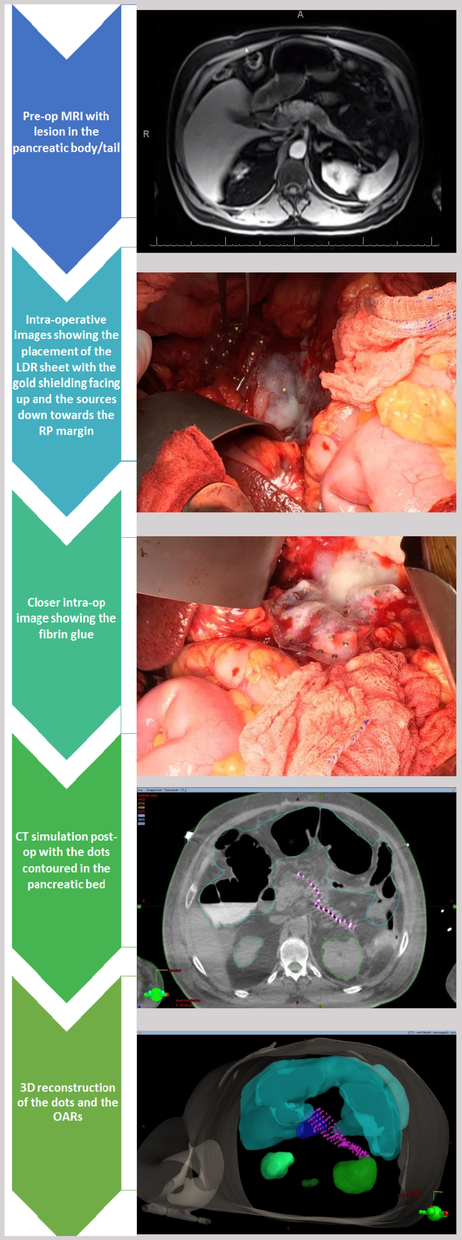
Patient Characteristics

- Between 3/2017 and 5/2018, 5 patients received LDR sheets at the time of surgery for pancreatic adenocarcinoma

Patient	Age (yrs)	Pre-op Stage	Pre-op Treatment
1	70	Resectable	None
2	51	Borderline	4 c FOLFIRINOX, gemcitabine-based chemoRT to 50.4Gy
3	72	Borderline	5 c FOLFIRINOX, gemcitabine-based chemoRT to 50.4Gy
4	61	Borderline	6 c FOLFIRINOX, gemcitabine-based chemoRT to 50.4Gy
5	63	Borderline	6 c FOLFIRINOX 5-FU based chemo RT to 50.4Gy 6 c FOLFIRINOX
Median (range)	63 (51-72)		

- The average procedure time was 7 hours and 17 minutes and the median time was 6 hours and 41 minutes
- The surgeon felt that placing the LDR sheet added only 15 minutes to the overall time
- There were no post-op complications attributable to the sheet

Patient	Surgery	Technique	Device Secured	Procedure Time (hours)
1	Distal pancreatectomy	Laparoscopic converted to open	Fibrin glue	6:41
2	Pancreaticoduodenectomy with partial PV/SMV resection and autologous vein patch	Laparotomy	3-0 vicryl and fibrin glue	8:49
3	Pancreaticoduodenectomy	Laparotomy	Fibrin glue	6:08
4	Distal pancreatectomy	Laparoscopic	Fibrin glue	5:01
5	Distal Pancreatectomy with reconstruction of the celiac and hepatic arteries and vein interposition graft	Laparoscopic converted to open	3-0 vicryl and fibrin glue	9:46



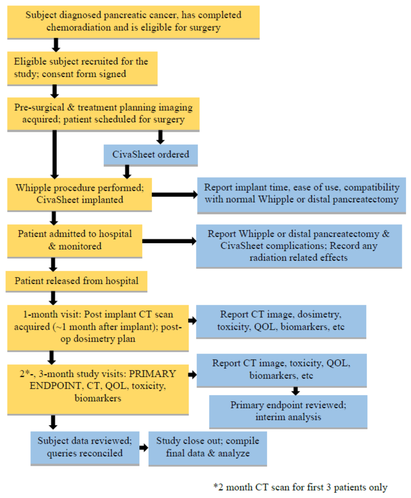
Patient Outcomes

- At a median follow up of 10 months, 1 patient has died related to a rare pulmonary complication of gemcitabine with no evidence of disease.
- One patient is alive with local and distant recurrence at 13 months and the other 3 are alive with no evidence of disease at 3, 10 and 13 months.

Patient	Follow up interval (months)	Disease Status	Time to recurrence
1	5	Dead, no disease	NA
2	13	Alive with disease	6 months
3	13	Alive no disease	NA
4	10	Alive no disease	NA
5	3	Alive no disease	NA
Median (range)	10 (3-13 months)		

SUMMARY & CONCLUSIONS

- This is the first study to report the safety and feasibility of the implantable, uni-directional, LDR brachytherapy CivaSheet in pts with a concern for close margins at the time of pancreatectomy.
- This novel, uni-directional, Pd-103 sheet provides a unique solution to the challenging problem of boosting these pts and will hopefully show improved rates of local control and ultimately overall survival in these pts.
- There is a Phase I/II study currently enrolling patients after neoadjuvant chemotherapy then chemoradiation or SBRT who have a risk of a close margin at the time of resection



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