

Clinical Use of a Novel Balloon Based Esophageal Brachytherapy Applicator

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Purpose

We report on the clinical implementation of a newly designed balloon applicator for high dose rate treatment of esophageal cancer.

Impetus

Review of our institutional experience with

Esophageal HDR:

- Well tolerated, **BUT ...**
- High rate of local recurrence
- Need to overcome surface dose limitation
- Significant increase in Grade 3 toxicity for single fraction doses above 15 Gy from SBRT spine treatments (Cox et al 2012).

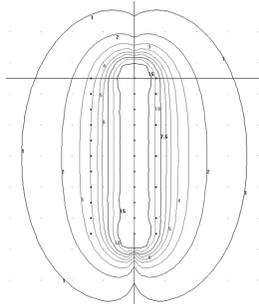
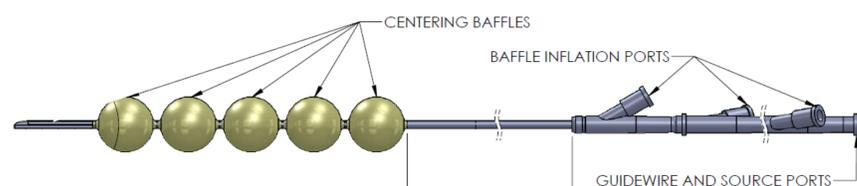


Table 1
Calculated mucosal doses (assuming 5-cm treatment length, 5 Gy per fraction)

Applicator outer diameter (mm)	Prescribed to 10 mm from source		Prescribed to 5 mm from applicator surface	
	Maximal dose Gy (% prescription)	Central dose Gy (% prescription)	Maximal dose Gy (% prescription)	Central dose Gy (% prescription)
4	78 (1550)	32 (636)	43 (856)	23 (450)
5	53 (1054)	23 (458)	31 (628)	19 (372)
6	38 (768)	19 (372)	26 (524)	15 (308)
8	23 (454)	13 (266)	23 (460)	14 (272)
10	16 (314)	11 (216)	16 (314)	11 (216)
12	12 (232)	9 (176)	13 (266)	10 (200)
14	9 (178)	7 (148)	12 (232)	9 (188)
15	8 (158)	7 (138)	11 (226)	9 (185)
16	7 (144)	6 (128)	11 (218)	9 (183)
20	5 (104)	5 (100)	10 (192)	8 (162)

Esophageal Balloon Applicator



- 5 independently controlled balloons
- 2 cm (up to 2.3 cm) balloon diameter
- 10 cm treatment length w/ incorporated X ray markers
- 5 mm shaft diameter w/ central source lumen; guide wire lumen
- May used with oral or nasal insertion methods
- Disposable (single use device)
- CT Compatible and MRI safe

Acknowledgments/Disclosures

- FDA 510(k) approved
- Developed in collaboration with Ancer Medical
- Patent pending

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Clinical Implementation

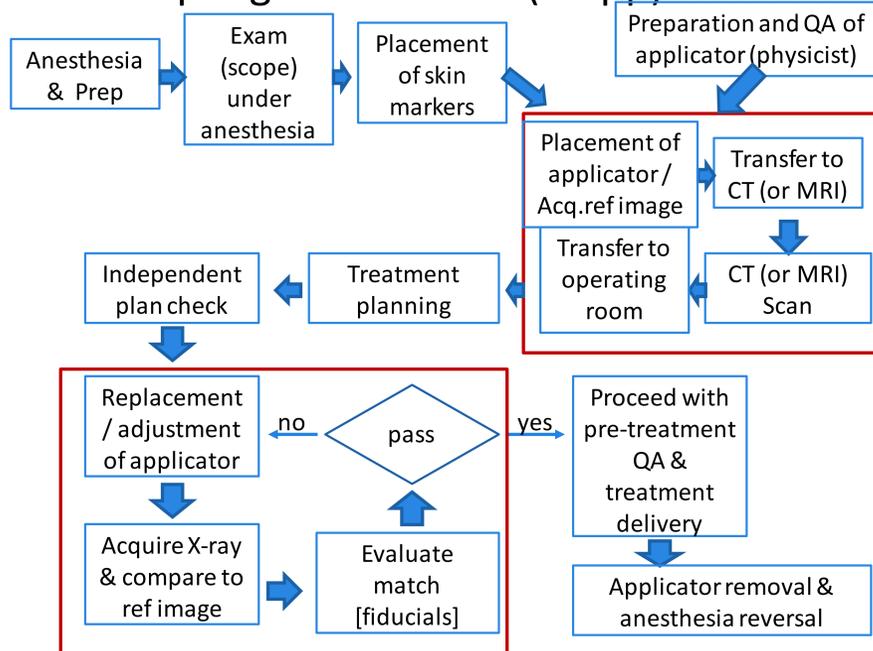
We maintained overall treatment regimen and clinical workflow, namely:

- 5 Gy x 3 weekly fractions + chemotherapy
- Endoscopy and fluoroscopy guidance

Changes introduced are:

- CT simulation & CT image based planning
- Dose prescribed to the entire volume

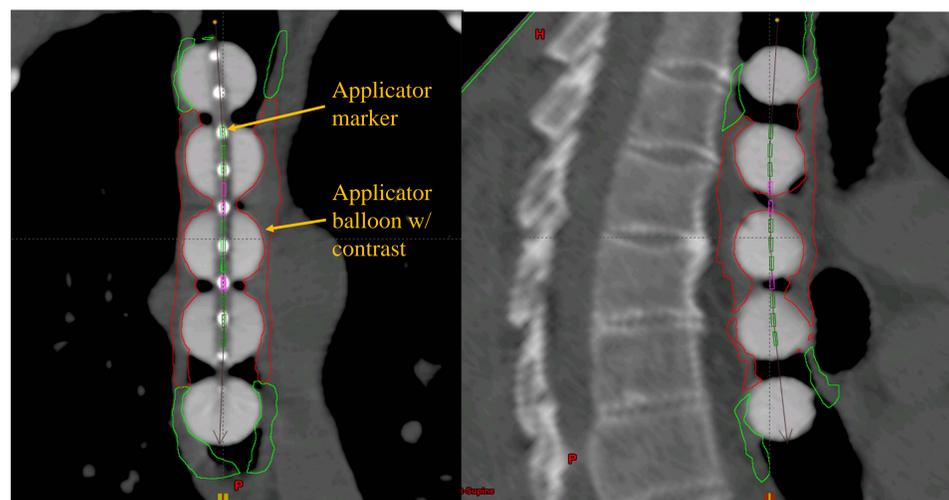
Esophagus Procedure (E-app) workflow



Treatment Planning

1. Contouring:

- Target = Affected Esophageal lumen
- Normal Esophagus = Esophageal lumen above and below target



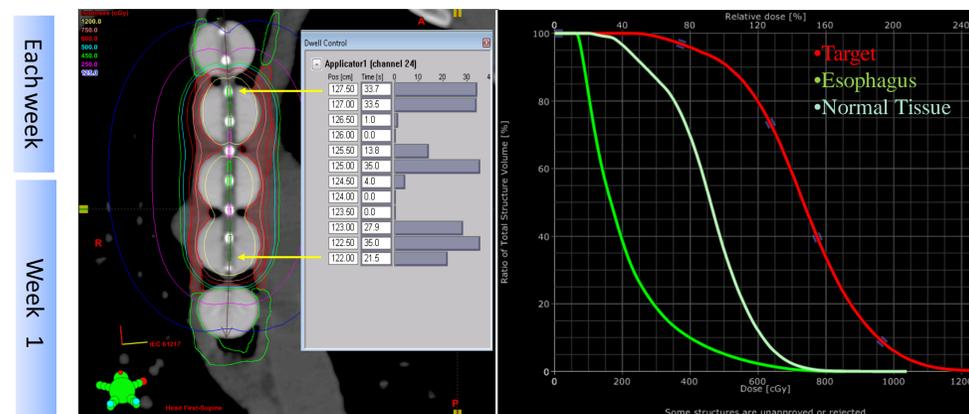
2. Plan optimization

- Target: V100 > 90%; D_{0.3cc} ≤ 11 Gy
- Normal Tissue (margin around target) minimized for dose conformity
- Normal Esophagus minimized, e.g. D_{0.3cc} ≤ 120%

3. Planing results

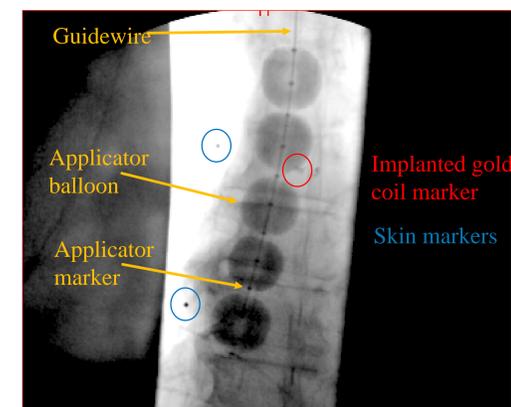
- Highly modulated dwell times

i.e. need to reproduce applicator position for each treatment



Treatment verification

- Use 10% contrast (Omnipaque) in balloons
- Implanted fiducial marker (e.g Visicoil) ideal but not always feasible
- traditional tools:
 - skin markers, anatomic landmarks
 - endoscopic verification
 - insertion depth



Conclusion

A multi-institutional study is being initiated to test the efficacy of these treatments and explore dose escalation in these patients, using this applicator.

References:

- Folkert MR, Cohen GN, Wu AJ et al. Endoluminal high-dose-rate brachytherapy for early stage and recurrent esophageal cancer in medically inoperable patients, Brachytherapy 12(5):463-70, 2013.
- Cox BW, Jackson A, Hunt M, et al. Esophageal toxicity from high dose, single-fraction paraspinal stereotactic radiosurgery. Int J Radiat Oncol Biol Phys 83:e661-e667, 2012.