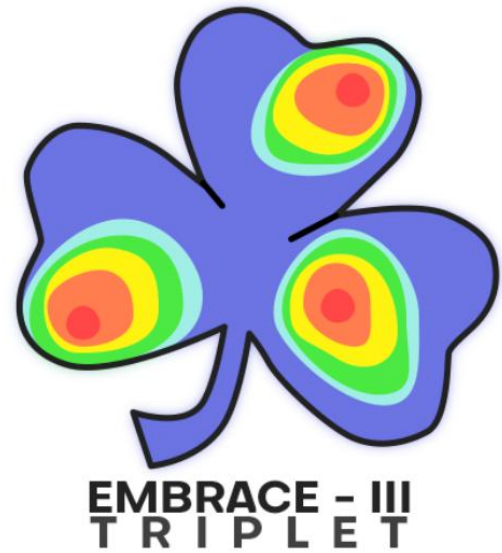


EMBRACE III – TRIPLET IMPACT STUDY



Integration of Multi-modality imaging Protocols

with emphAsis On

CT in Image Guided Adaptive Brachytherapy (IGABT)

In Cervical Cancer

(Analogous to EMBRACE I Study)

STUDY OFFICE:

- MEDICAL UNIVERSITY VIENNA (DATA CENTRE)
- HOMI BHABHA CANCER HOSPITAL & RESEARCH CENTRE, TATA MEMORIAL CENTRE, VISAKHAPATNAM, INDIA

BACKGROUND


CT based target contouring supplemented by other imaging - Ultrasound, Pre BT MR etc.

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Original Article

IBS-GEC ESTRO-ABS recommendations for CT based contouring in image guided adaptive brachytherapy for cervical cancer

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Prospective Studies – Validation & Clinical Outcome Essential

HIGHLIGHTS OF THE CT RECOMMENDATIONS

III. Defining different Clinico-radiological environments

Based on Surveys with all the network members

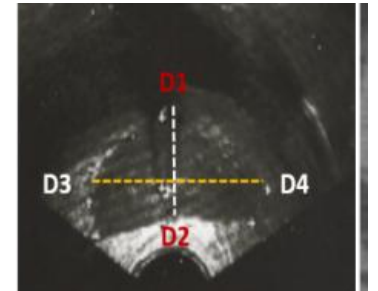
Prospective Evaluation - 2 CT Environments

1a. Real time TRUS during BT and CT at BT (1.2 & 2.2)

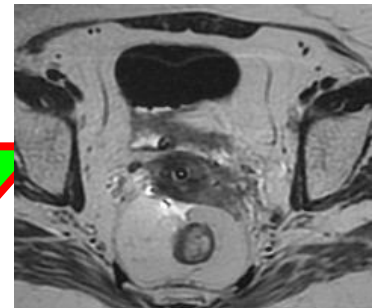
1b. Pre BT MR and CT at BT (3.2 & 4.2)

2. CT at BT only (1.1)

TRUS during BT



Pre BT MR



Validation study for IBS-GEC ESTRO-ABS Recommendations: Mono-Institutional Series

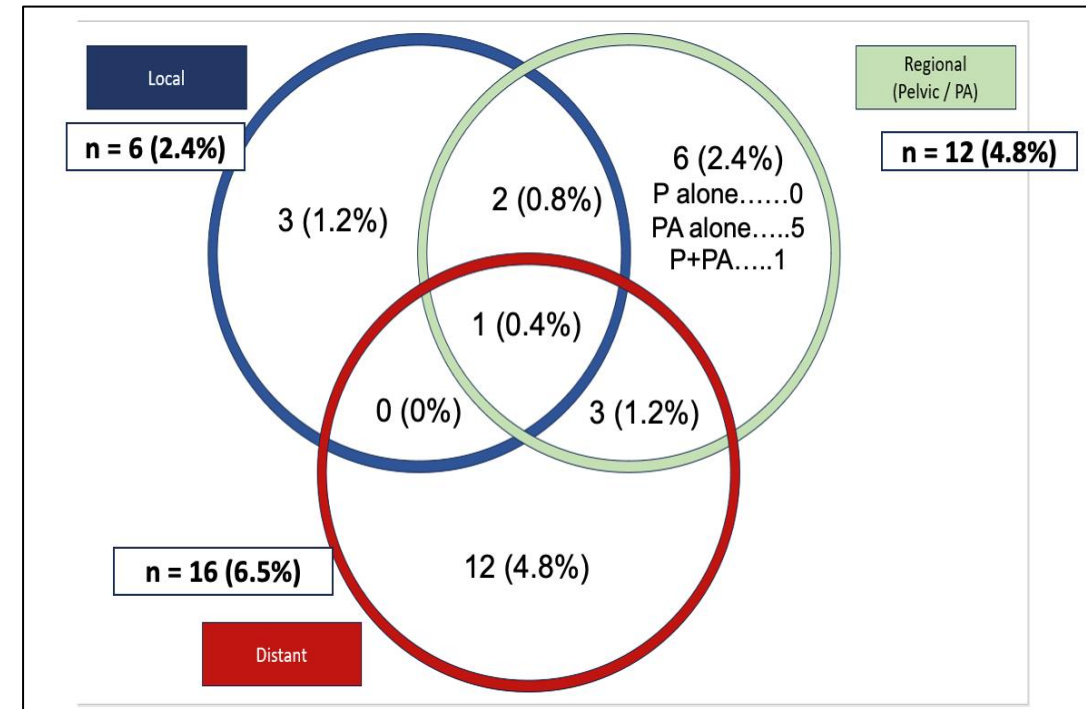
Early Clinical Outcomes of Cervical Cancer treated with CT based Image Guided Adaptive Brachytherapy (RETRO LACER STUDY)

At Homi Bhabha Cancer Hospital & Research Centre, Visakhapatnam

Consecutive patients treated between
1st Aug. 2020 – 31st July 2023
Screened for Inclusion (N = 318)
N: 245 pts

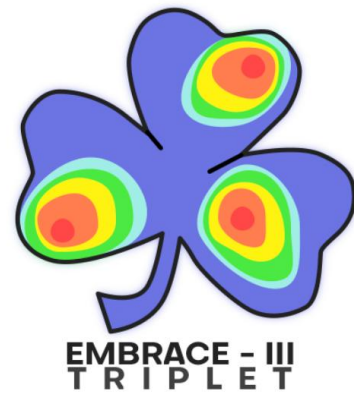
BT Environment [Defined as per upcoming CT-IGABT Registration Study under EMBRACE 3]	n (%)
<u>Basic CT Environment</u> [MR/CT at Diagnosis] + [CT at BT]	158 (64.5%)
<u>Advanced CT Environment</u> [MR/CT at Diagnosis] + [(Pre BT MR / TRUS) with CT at BT]	87 (35.5%)

Median follow up – 17 months



EMBRACE - III TRIPLET: IMPACT STUDY

Multi-centre Prospective International Study



Aims:

Overall:

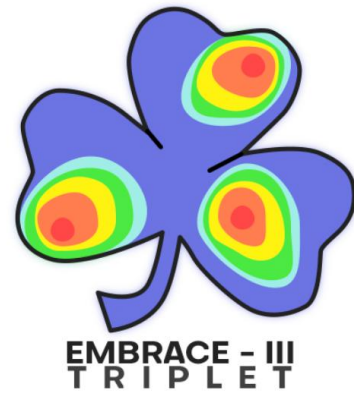
- To implement advances in cervical cancer BT including *advanced BT application & a CT imaging environment as alternatives to MR IGABT* towards achieving access to care and from an implementation

Specific:

- To introduce CT based Image Guided Adaptive BT (CT-IGABT) in locally advanced cervical cancer in a multi-centre setting within the framework of a prospective observational study
- To explore feasibility and reproducibility of implementing IBS GEC-ESTRO ABS CT based target definition recommendations in locally advanced cervical cancer in a multi-center setting
- To establish a benchmark for clinical outcome in a large real world patient population treated with CT-IGABT, with respect to local control, survival, morbidity, and quality of life (QoL)

EMBRACE - III TRIPLET: IMPACT STUDY

Multi-centre Prospective International Study



A. Cohort A: Advanced CT BT Environment

- *CT or MR at Diagnosis*

& Either (1) Pre BT MR or (2) TRUS & CT at BT mandatory for all applications

B. Cohort B: Basic CT BT Environment

- *CT or MR at Diagnosis & CT only at BT mandatory for all BT Applications*

IMPACT study will be opened for accrual for

Advanced CT Environment followed by Basic CT Environment

Participating Centre selection:
(To maintain the uniformity in Quality of treatment)

Minimum requirements for centres to participate in the study will be as follows

- **Staging:** Cross sectional imaging of thorax, abdomen and pelvis (**CT or MR or PET-CT**)
- **Treatment :** Both EBRT and BT performed at the same centre
- **EBRT: 3DCRT as a minimum; IG-IMRT allowed** as per institutional practice
- **Brachytherapy: Predominantly HDR BT**
 - *Access to Pre-Brachy MRI or Biplanar TRUS during BT Application*
 - *Advanced CT/ MR compatible GYN Applicators including IC+IS tech when needed*
 - *CT imaging with applicator in situ for BT for all applications*
 - *CT based brachytherapy planning with dose-volume based prescription*

Patient Selection & Outcomes

a. Inclusion criteria:

- Cervical cancer considered suitable for curative treatment with **definitive chemoradiotherapy including brachytherapy**
- Biopsy showing invasive SCC or adenocarcinoma or adeno-squamous cell carcinoma
- **FIGO (2018) stage IB2 to IV A**

b. Exclusion criteria:

- Other previous or current primary malignancies except carcinoma in situ of the cervix or skin cancers
- **Metastatic disease beyond para-aortic region (L1-L2)**
- Small cell carcinoma histology
- Previous pelvic or abdominal radiotherapy
- Previous total or partial hysterectomy
- Patients receiving BT only
- Patients receiving EBRT only
- **Patients receiving any form of neoadjuvant anti-neoplastic therapy prior to definitive treatment**
- Active infection or severe medical condition which precludes radical chemoradiotherapy
- Pregnant or lactating or childbearing potential without adequate contraception

Primary Endpoints:

- ***Local control*** at 36 months and \geq ***Grade 3 morbidity***

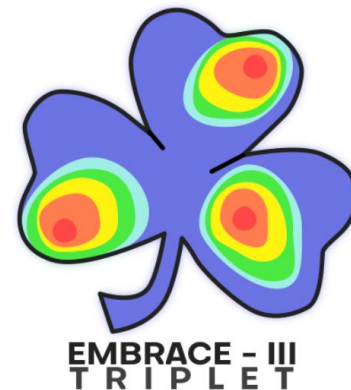
Secondary endpoints:

- *Regional control, DFS & OAS*
- *Descriptive comparison with Retro-EMBRACE, EMBRACE I & II and other cohorts of IGABT as and when available*

THE MINI QUALITY OF LIFE QUESTIONNAIRE: GYNAECOLOGICAL CANCERS






Rate the following questions with regard to how you have felt over the last 1 week

QOL STUDY (OPTIONAL)



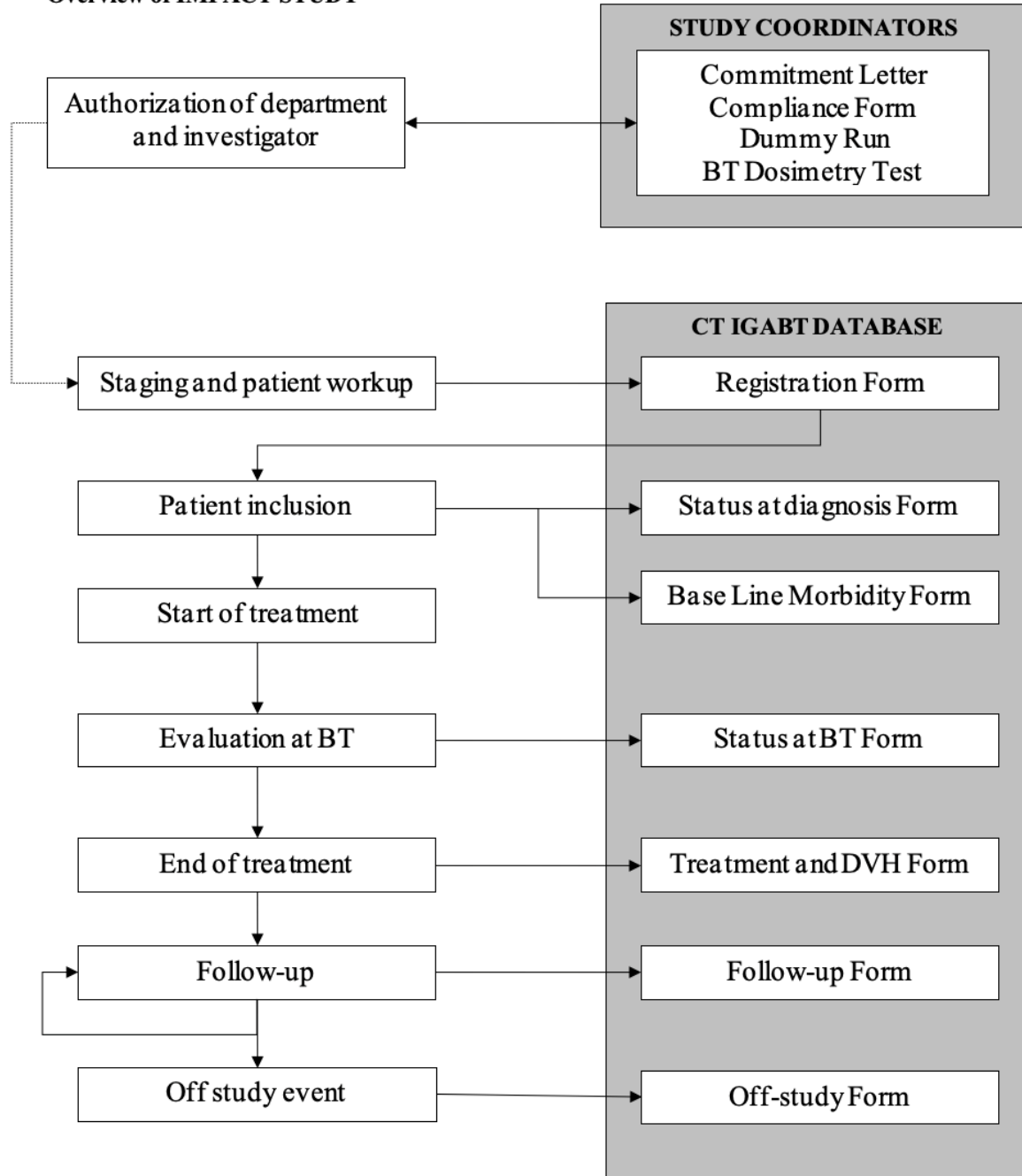
TMQ GYN Tool

- Simple & practical QOL questionnaire
- Validated with EORTC QLQ 30, Cx 24 & Ov 28
- Suitable to use in busy clinics esp. LMIC's

						
		0	1	2	3	4
1.	How much pain have you had?	Not at all	A little	Somewhat	Quite a lot	Very much
2.	Are you able to perform your daily activities and self-care?	Can do everything as before	Can do most things as before	Need help sometimes	Need help with most things	Cannot do anything independently
3.	Are you eating well?	Normal as before	Eat less than before	Eat with difficulty	Can eat a little	Cannot eat at all
4.	Is your sleep disturbed?	Not at all	A little	Somewhat	Quite a lot	Very much
5.	Have you had nausea or vomiting?	Not at all	A little	Somewhat	Quite a lot	Very much
6.	Have you had diarrhea or constipation?	Not at all	A little	Somewhat	Quite a lot	Very much
7.	Are you concerned about your appearance or body image?	Not at all	A little	Somewhat	Quite a lot	Very much
8.	Do you lack support and help from family and friends?	Not at all	A little	Somewhat	Quite a lot	Very much
9.	Is the relationship with your husband/wife/life partner affected?	Not at all	A little	Somewhat	Quite a lot	Very much
10.	Do you worry about your or your family's future?	Not at all	A little	Somewhat	Quite a lot	Very much
11.	Do you have financial worries?	Not at all	A little	Somewhat	Quite a lot	Very much
12.	How is your experience with people providing medical care to you?	Very Good	Good	Average	Bad	Very Bad
13.	Are you troubled by vaginal or rectal bleeding or discharge?	Not at all	A little	Somewhat	Quite a lot	Very much
14.	Do you experience any urinary difficulty?	Not at all	A little	Somewhat	Quite a lot	Very much
15.	How much is your overall quality of life affected?	Not at all	A little	Somewhat	Quite a lot	Very much

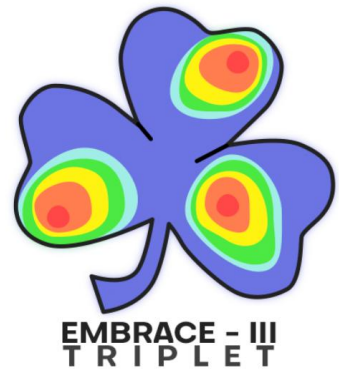
Is there anything else which bothers you or affects your quality of life?

Overview of IMPACT STUDY



EMBRACE - III TRIPLET: IMPACT STUDY

Multi-centre Prospective International Study



Training Modules:

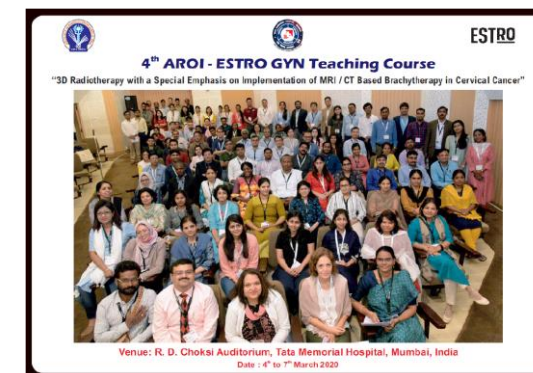
*Online & Offline Training Modules related to various key features of the protocol – **In progress***

- 1. Modified Clinical Drawings & Documentation of NMD's at diagnosis & BT applications.**
- 2. Ultrasonography: TAUS & TRUS protocol during BT Application –and documentation of findings**
- 3. CT Imaging protocol with BT Applicator in place**
- 4. Target & OAR Contouring on CT**

All Training tools on Brachyterra

<https://brachyterra.thinkific.com/>

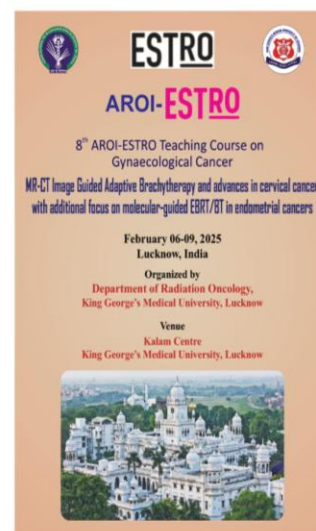
AROI - ESTRO GYN TEACHING COURSES IN INDIA: 2017- 2024



TRAINING & EDUCATION IN IGABT IN INDIA & NEIGHBOURING COUNTRIES

Gynae Course	2017	2018	2019	2020	2022	2023	2024
Clinicians	39	78	71	58	74	76	112 (ONLINE: 50)
Physicists	23	18	25	30	39	22	22
Total Participants	62	96	96	88	113	98	134
Same as 2017		14	9				
Same as 2018			15	24	16	14	25
Same as '17 & '18			7				
Institutions	31	49	56	45	52	42	60

2020 Onwards: IAEA + Neighbouring countries participation



TEAM OF RAD ONCO & MEDICAL PHYSICISTS – SR / JUNIOR FACULTY TO PARTICIPATE

APAC Countries:

- India (6-8 centers thru AROI ESTRO Gyn Teaching Course participants)
- Japan (Gunma), Thailand (Chiang Mai), Hongkong, Philippines (Manila), Indonesia (Jakarta),

Brazil (Sao Paulo), Egypt (Cairo),

Africa (Botswana),

South Africa (Johannesburg)....

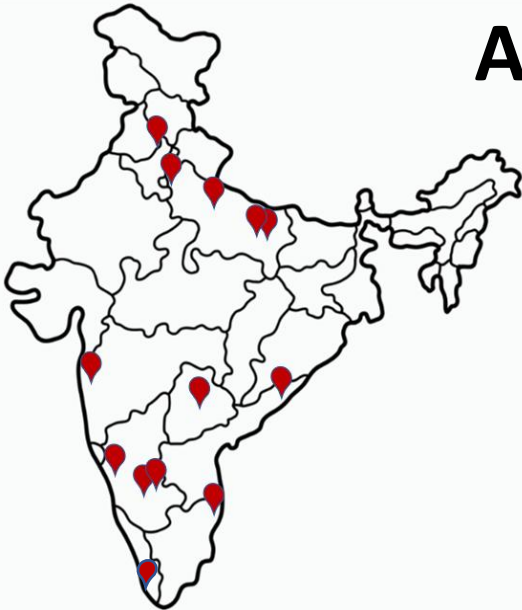
North America-

East Europe -

AROI Research Network on GYN Cancers – Kolkata July 2022

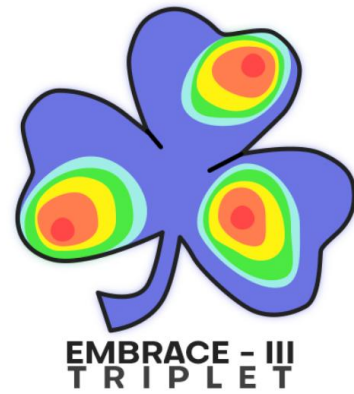


AROI ESTRO GYN TC (Advanced track) : 13 Institutions



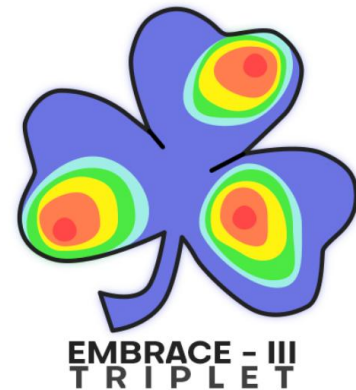
- Feasibility of TRUS : 4-6 centres
- Feasibility of Pre-BT MRI – 13 centres
 - Feasibility of CT alone - 13

UPDATES & TIMELINES – MARCH 2025



- **LOCAL ETHICS APPROVAL – Submitted in MARCH 2025**
- **TEMPLATES BEING FINALIZED: APRIL – MAY 2025**
 - *DUMMY RUN EVALUATION PROTOCOL*
 - *SITE INITIATION MEETING (ONLINE / OFFLINE) & TRAINING MODULE*
 - *PERIODIC AUDITS – PATIENT SPECIFIC / OVERALL MODULE*
- **Clinical trials Registration: MAY 2025**
- **ACTIVATION OF THE PROTOCOL ON WEBSITE: JUNE – JULY 2025**
- **WEB DETAILS FOR REGISTRATION & e-CRF DATA ENTRY : APRIL – MAY 2025**

ACKNOWLEDGEMENTS



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Ina Schulz,

Jacob Lindegaard

Stefan Ecker

Dragan Misimovic

Richard Potter

&

Many others.....

WATCH OUT FOR MORE INFO

IN

MAY- JUNE 2025!

drumeshm@gmail.com

THANK YOU!