A randomized phase III study comparing Neoadjuvant chemotherapy followed by concurrent chemo-radiotherapy with concurrent chemo-radiotherapy in Asian-Indian (South Asian) population with muscle invasive bladder cancer

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Disclosure slide

- No conflicts of interest to declare

Introduction

- Bladder cancer accounts for 3% of all cancer
- M:F :: 4:1
- Age adjusted incidence rate 5.5/100000 population in india
- 429,800 new cases of bladder cancer and 165,100 deaths occurred in 2012 worldwide
- About a 10-fold variation in incidence rates internationally. incidence rates are highest in europe, northern america, western asia, and northern africa

Introduction

- Main treatment of muscle invasive bladder cancer is surgery with or without radiotherapy
- Organ-preserving approach is a new trend

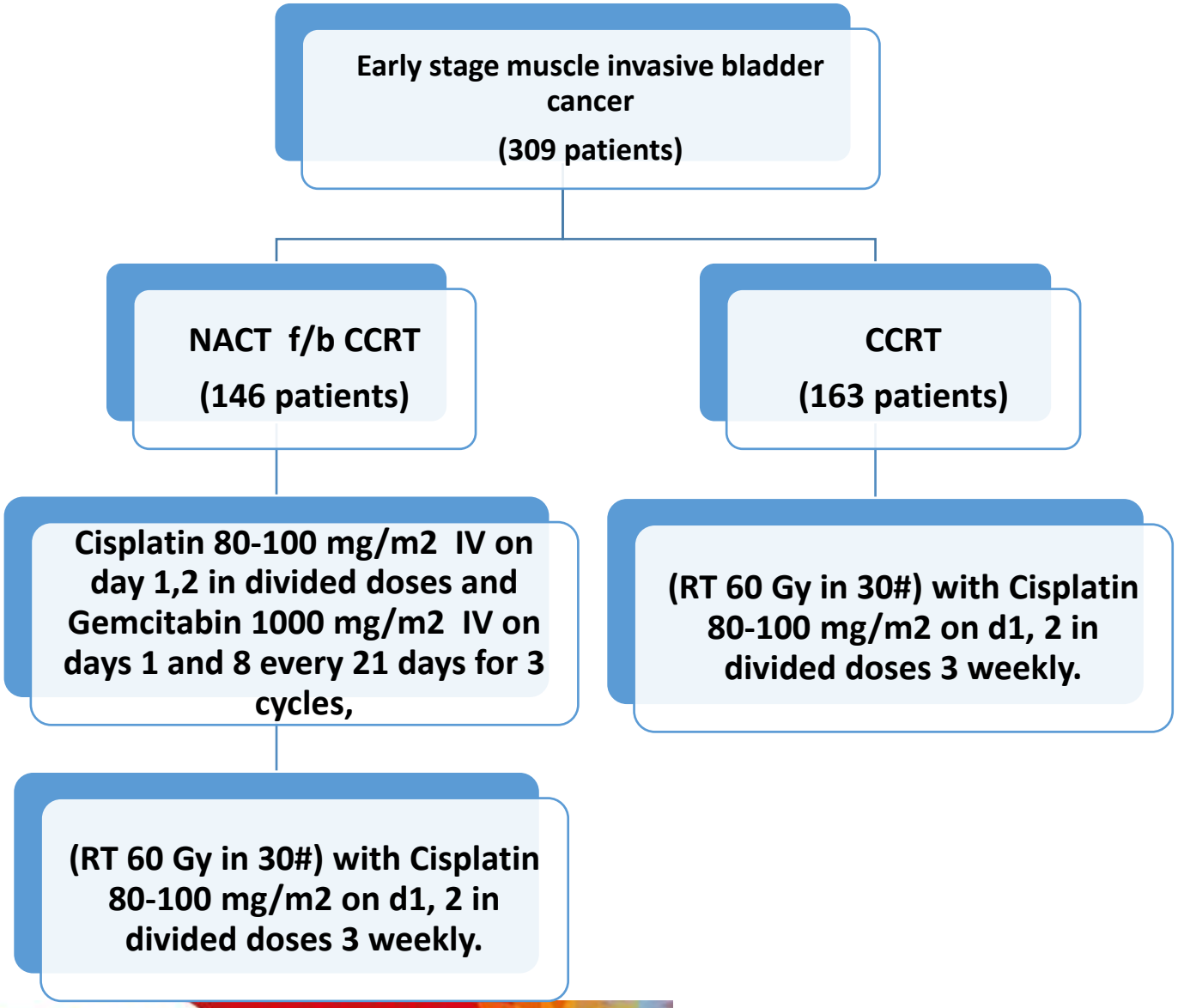
Aims

- The aim of this study to identify the additional benefit for bladder preservation, survival and toxicity, in Indian Asian population with muscle invasive early bladder cancer.

Materials & Method

- The histo-pathologically proven transitional cell cancer by TURBT
- Muscle invasive early bladder cancer (cT2-cT4a).
- Patients were randomly enrolled
- All statistical calculations were performed using SPSS version 20.0 software.

Materials & Method



Patient characteristics

S. no.	NACT → CCRT arm (n=146)	CCRT arm (n=163)
Age (years) **Median (range)**	**60 (49-70)**	**63 (52-68)**
Gender **Male** **Female**	**124** **22**	**134** **29**
ECOG **0-1** **2**	**135** **11**	**148** **15**
TNM stage **II** **III**	**50** **96**	**64** **99**
Smoking History Yes No	**107** **39**	**114** **49**

RESULTS

- The 3 year bladder preservation in NACT f/b CCRT arm patients has 62%
- CCRT arm have 54% (8% benefit at 3 years in study arm).
- The median PFS was 26.9 months (95% CI; 23.1-30.5) for NACT f/b CCRT versus 23.1 months (95% CI;19-3-25.6) in the CCRT only arm (p=.59).
- Patients treated with NACT has more grade 2/3 GI and hematological toxicities, but were statistically insignificant.

conclusion

- NACT f/b CCRT was well tolerated and better with bladder preservation and PFS survival in Asian Indian population.