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 is 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

Early stage muscle invasive bladder cancer
(309 patients)

NACT f/b CCRT
(146 patients)
- Cisplatin 80-100 mg/m² IV on day 1, 2 in divided doses and
- Gemcitabin 1000 mg/m² IV on days 1 and 8 every 21 days for 3 cycles,

CCRT
(163 patients)
- (RT 60 Gy in 30#) with Cisplatin 80-100 mg/m² on d1, 2 in divided doses 3 weekly.
## Patient characteristics

<table>
<thead>
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<th>S. no.</th>
<th>NACT → CCRT arm (n=146)</th>
<th>CCRT arm (n=163)</th>
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</thead>
<tbody>
<tr>
<td>Age (years)</td>
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<tr>
<td>Median (range)</td>
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<tr>
<td>Gender</td>
<td>124 22</td>
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<td>Male</td>
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<td>114 49</td>
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<tr>
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<tr>
<td>III</td>
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</table>
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.
THANKS

Acharya Tulsi Regional Cancer Treatment & Research Institute, Bikaner, India