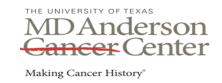
Quality of Life in Early-Stage Cervical Cancer Patients Undergoing Radical Hysterectomy via Minimally Invasive or Open Surgery: The LACC Trial

M. Frumovitz, A. Obermair, R. Pareja, A. Lopez, M. de Andrade Vieira, R. Ribeiro, A. Buda, X. Yan, K. Robledo, R. Asher, V. Gebski, V. Behan, R. Coleman, P. Ramirez





In collaboration with the Japanese Society of Gynecologic Oncology
UNITING THE GLOBE IN THE FIGHT AGAINST
GYNECOLOGIC CANCER



Faculty Disclosure

| | No, nothing to disclose | | | |
|---|-------------------------|--|--|--|
| Х | Yes, please specify: | | | |

| Company Name | Honoraria/ Expenses | Consulting/ Advisory Board | Funded Research | Royalties/ Patent | Stock Options | Ownership/ Equity Position | Employee | Other (please specify) |
|---------------------|------------------------|-------------------------------|--------------------|----------------------|------------------|----------------------------------|----------|---------------------------|
| Stryker | X | X | Х | | | | | |
| Navidea | | | Х | | | | | |
| Ipsen | | Х | | | | | | |
| Genetech | | Х | | | | | | |
| Johnson and Johnson | Х | | | | | | | |

Off-Label Product Use

| Will you be presenting or referencing off-label or investigational use of a therapeutic product? | | | | | |
|--|----------------------|--|--|--|--|
| X | No | | | | |
| | Yes, please specify: | | | | |

LACC Study Schema

R

D

0

M

Open: June 2008

Accrual: 631

Closed: June 2017*

Stage IA1 LVSI,
IA2, IB1
Squamous,
Adenocarcinoma, or
Adenosquamous
Cervical Cancer

Radical

Total Abdominal Radical Hysterectomy

N = 312

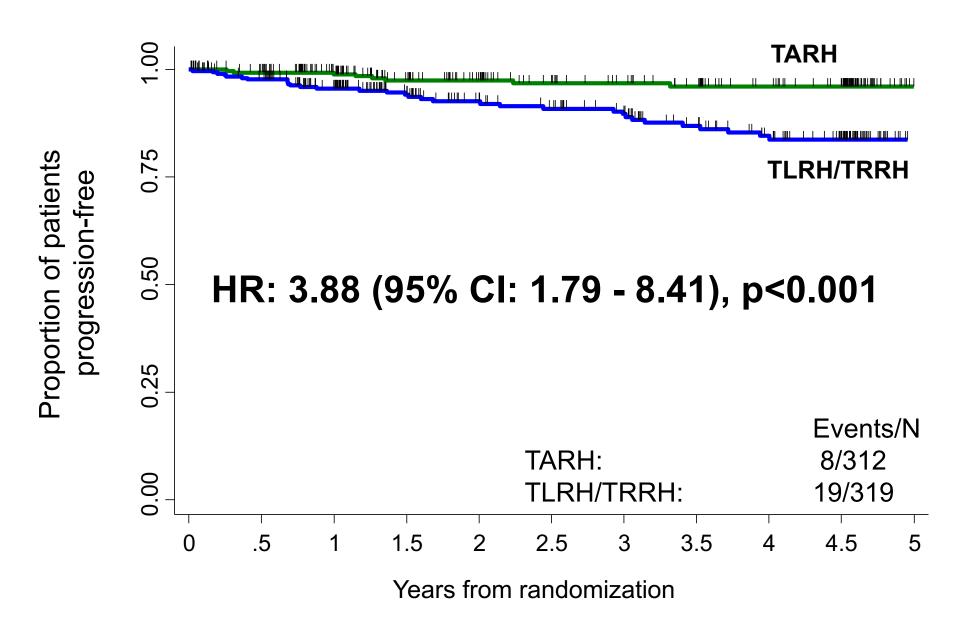
Total Laparoscopic/Robotic Radical Hysterectomy

N = 319

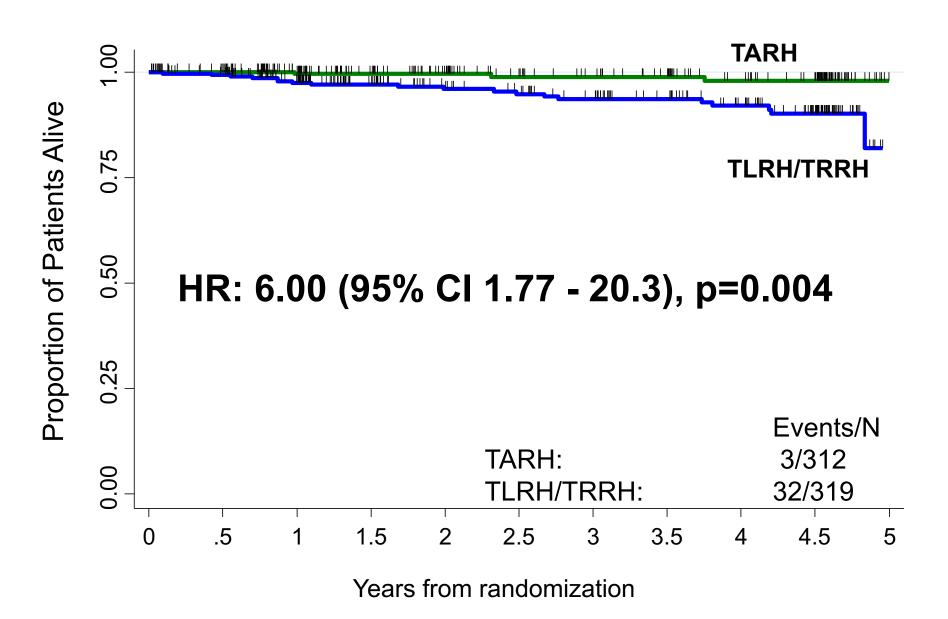


^{*}Recommendation of study termination by DSMC

Progression-Free Survival (PFS)



Overall Survival (OS)



LACC Trial Objectives

Primary: Disease Free Survival

Secondary: Overall Survival

Patterns of Recurrence

Treatment-Associated Morbidity

Cost-Effectiveness

Pelvic floor Dysfunction

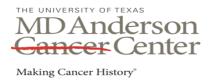
Feasibility of Sentinel Nodes

Quality of Life



Quality of Life Instruments

- Functional Assessment of Cancer Therapy Cervix (FACT-Cx)
 - Cancer specific (cervical) conditions or symptoms
- Short Form-12 (SF-12)
 - Generic health concepts
- MD Anderson Symptom Index (MDASI)
 - General symptoms and their effect on overall well-being
- EuroQol -5D (EQ-5D)
 - General health outcomes



Methods

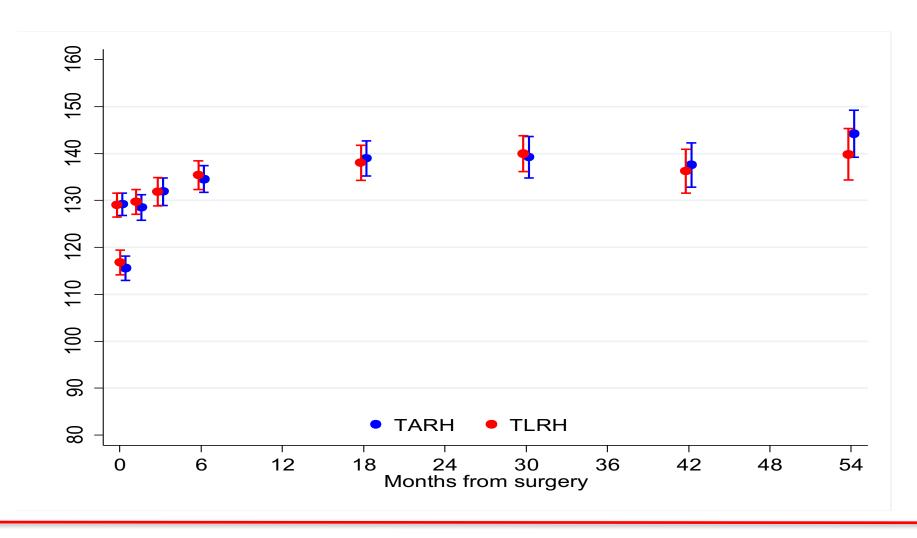
- Self administered
- 78 total items
- Timepoints: Preoperatively (baseline)
 - 1 week postoperatively
 - 6 weeks postoperatively
 - 3 months postoperatively
 - 6 months postoperatively
 - q 12 months thereafter (FACT-Cx only)



Demographics

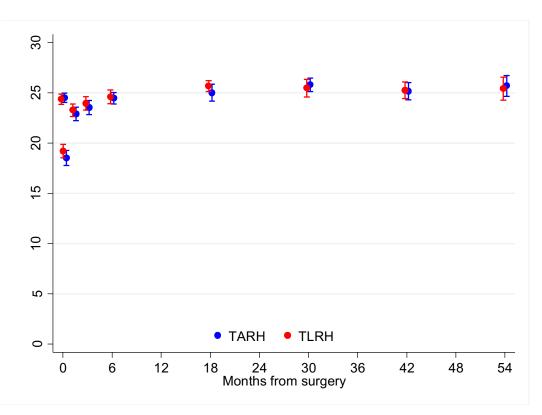
| | Open | MIS | | |
|----------------------------------|-------------|-------------|--|--|
| Characteristic | (n=312) | (n=319) | | |
| Mean age, yr (SD) | 46.0 (10.6) | 46.1 (11.0) | | |
| Mean BMI, kg/m ² (SD) | 26.2 (5.3) | 27.2 (5.6) | | |
| Geographic Region, n (%) | | | | |
| Asia | 63 (20) | 63 (20) | | |
| Australia/New Zealand | 48 (15) | 46 (14) | | |
| Europe | 27 (9) | 32 (10) | | |
| North America | 49 (16) | 45 (14) | | |
| South America | 125 (40) | 133(42) | | |
| Type of incision, n (%) | | | | |
| Vertical midline | 156 (50) | | | |
| Low transverse | 118 (38) | | | |
| Did not undergo open surgery | 38 (12) | | | |

FACT-Cx Total Score

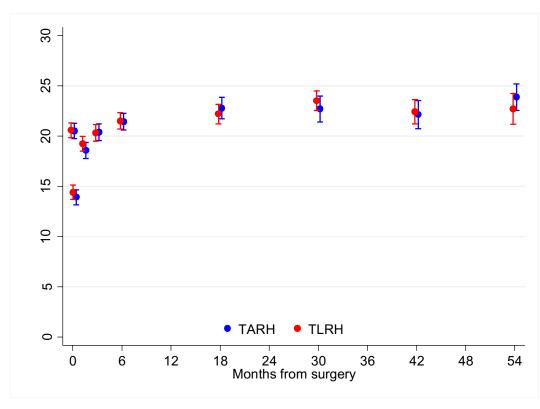




FACT-Cx Subscales



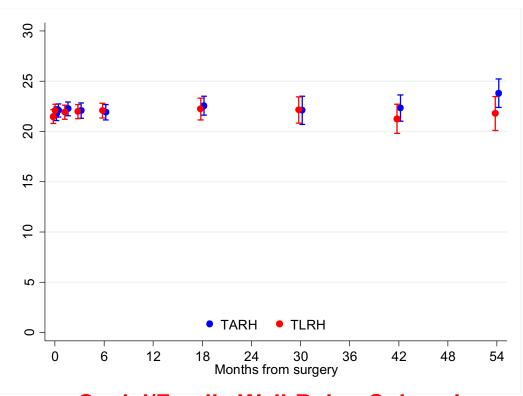
Physical Well-Being Subscale



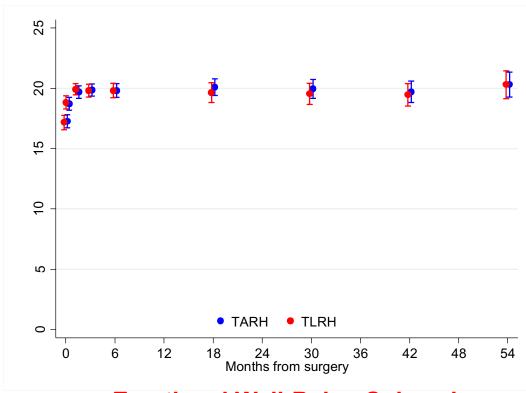
Functional Well-Being Subscale



FACT-Cx Subscales



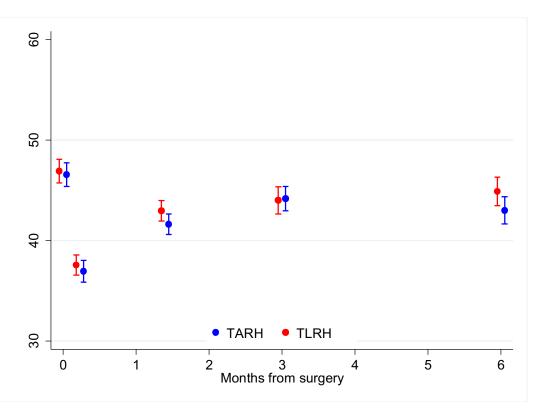
Social/Family Well-Being Subscale



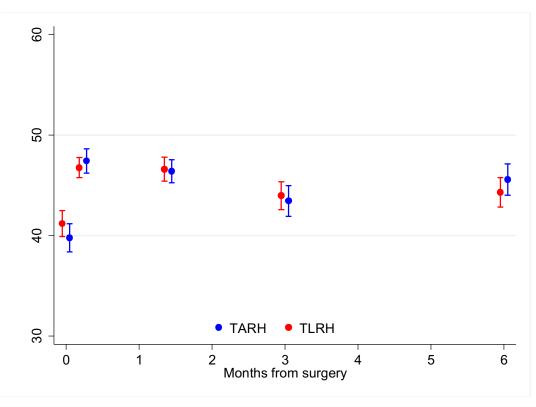
Emotional Well-Being Subscale



SF-12 Scores



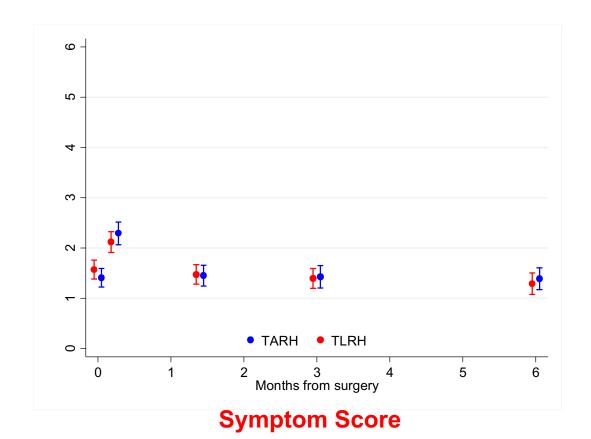
Physical Component Score (PCS)



Mental Component Score (MCS)



MDASI Scores

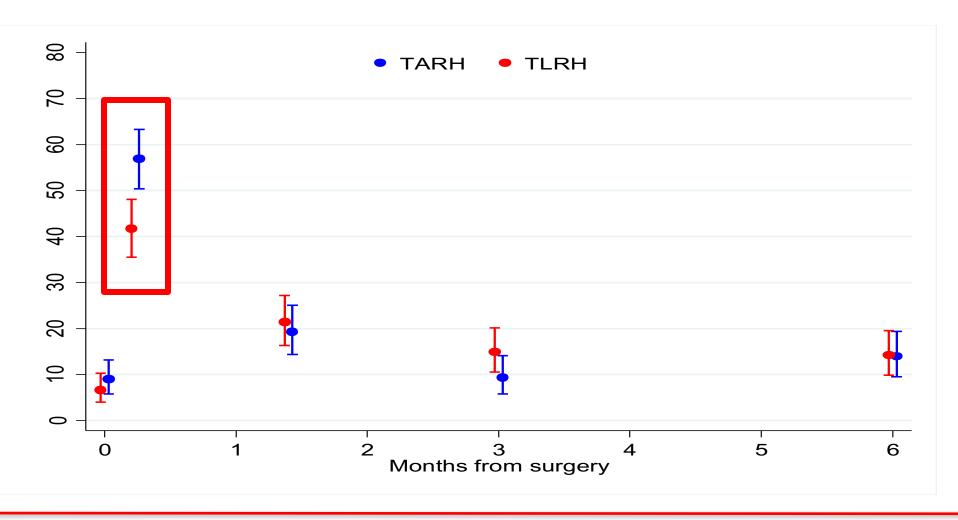


9 2 4 က • TARH • TLRH 0 3 Months from surgery **Interference Score**



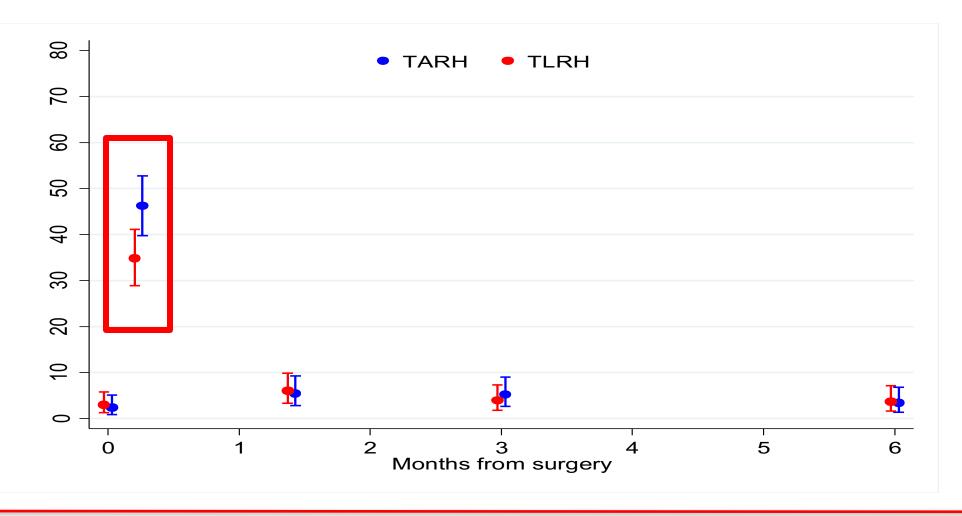
Making Cancer History®

EQ-5D Mobility Score





EQ-5D Self-Care Score





Conclusions

- Almost all general and disease specific HRQoL similar for both groups at 1 week postoperatively and thereafter
- Mobility is decreased in open surgery group at 1 week
 - Difference resolves by 6 weeks postoperatively



How Are You Going to Counsel Your Patients?

- No difference in QoL at 1 week and beyond (except mobility)
- No difference in intraoperative complications
- No difference in short- or long-term morbidities
- Almost 4x more likely to recur with MIS radical hysterectomy
- 6x more likely to die after MIS radical hysterectomy



Thank You



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