



Breast Conservation or Mastectomy? A Randomized Controlled Trial of the Navya Patient Preference Tool An Online Self-Administered Adaptive Conjoint Analysis Based Decision Aid

Naresh Ramarajan¹, Shalaka Joshi², Lakshmi Ramarajan³, Gitika Srivastava¹, Sudeep Gupta², Nita Nair², Rajendra Badwe²
1. Navya Network, Cambridge, MA, USA 2. Tata Memorial Centre, Mumbai, India 3. Harvard Business School, Cambridge, MA, USA

Background

- **Choice confronting women diagnosed with early breast cancer:** Breast Conservation Therapy (BCT) OR Mastectomy?
- **Women's ability to make their own medical decision impacted by:**
 - Access to information and decision aids
 - Gender identity
 - Shared autonomy with key male family members
 - Role in her family
- **Current decision aids are limited:**
 - Not designed to include the patient's key family members
 - Resource intensive when administered by clinical providers
 - Not easily available outside expert centers
- **Adaptive Conjoint Analysis based Navya Patient Preference Tool**
 - Powerful social sciences technique applied to medical decision making
 - Uncovers personal values driving patient preferences
 - Converts stated preferences into a specific treatment recommendation
- **How it works: Online and self-administered**
 - Resource efficient: Independent of a clinical encounter
 - Accessible anytime: at home or the clinic, alone or with family
 - Scalable: beyond boundaries of limited expert cancer centers

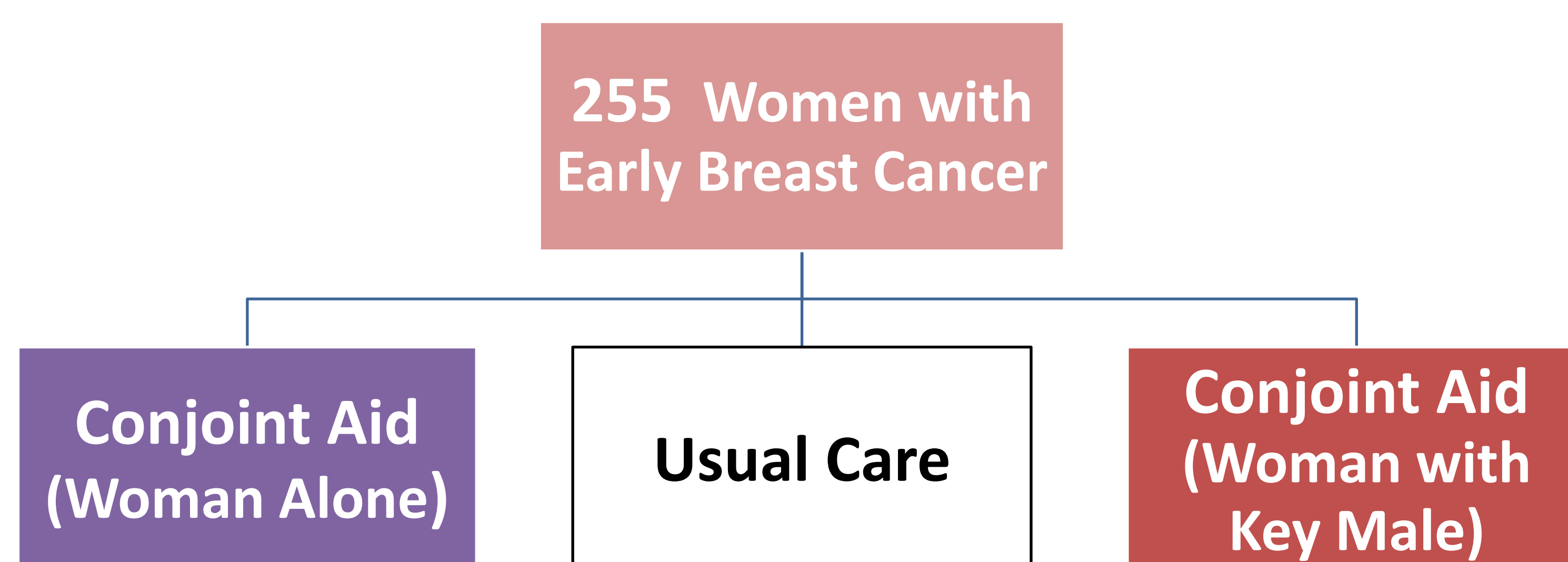
Methodology

- **Research and Trial Site:** **Tata Memorial Centre, Mumbai, India;** One of Asia's largest tertiary cancer centers
- **Design:** Randomized controlled trial
- **Sample Size:** 255 women in 1:1:1 randomization
- **Stratification:** Age, education and socioeconomic status
- **Eligibility Criteria:**
 - Women with node negative operable breast cancer are included.
 - Minors, pregnant women, and patients who cannot understand written consent or survey content are excluded
- **Outcome:**
 - **Primary Outcome is reduction in Decisional Conflict Index (DCI)**
 - Secondary Outcomes are Patient satisfaction with care, Concordance with Navya PPT, Follow through and mastectomy rate
- **Pre-specified subgroup analyses** by Autonomy Preference Index (API), Traditional-Egalitarian Gender Roles, and Family Embeddedness

Objective

- Navya PPT will reduce decisional conflict compared to usual care
- Participation of a woman's self-identified key family member will reduce decisional conflict, especially in women highly embedded in the family, with traditional gender identity or limited sense of autonomy.

RANDOMIZATION OF WOMEN 1:1:1 INTO THREE GROUPS



TRADEOFFS PRESENTED IN DECISION AID

BREAST CONSERVATION THERAPY	MASTECTOMY
KEEPING THE BREAST	LOSING THE BREAST
COST 50% MORE THAN MASTECTOMY	BASELINE COST
SIDE EFFECTS OF MANDATORY RADIATION	30% CHANCE OF RADIATION

EXAMPLE SCREEN: ADAPTIVE CONJOINT ANALYSIS TOOL

If you did not have to worry about anything else and only need to focus on two things, what do you prefer?

Keep breast. Breast will look the similar and retain most sensation. However, there will be scar. May need additional unplanned surgery if breast cancer cells reoccur.

Lumpectomy side effects, which may include:

1. less pain and scarring than Mastectomy

You will definitely need radiation therapy and experience radiation side effects, which may include: sore and painful skin in the treatment area, pigmentation in the skin

Breast is removed, but will not need any further surgeries in that location to remove breast cancer cells. Can have breast reconstruction surgery if choose to do so.

Mastectomy side effects, which may include:

1. pain in the scar for a long period of time,
2. numbness and tenderness along the scar, and
3. possibility of fluid collection (seroma) in the chest.

There is a 30% chance (i.e.1 out of 3, or small to medium chance) that you will need radiation therapy and experience radiation side effects, which may include: sore and painful skin in the treatment area

or

Strongly Prefer Left
 Somewhat Prefer Left
 Indifferent
 Somewhat Prefer Right
 Strongly Prefer Right

Conclusion

Through a large randomized controlled trial, we assess the benefit of a conjoint analysis based decision aid for women with early breast cancer. An online self administered tool has the potential to increase access to shared decision making.

We also study the impact of a woman's family role, gender identity, and sense of autonomy in breast cancer decision making. The explicit inclusion of key family members may enable access to shared decision making for women who are devoid of it.