

# Slip and slide

## Findings from the Sexual Activity after Breast Cancer (SAB) Study

Martha Hickey<sup>1</sup>, Jennifer L. Marino<sup>1</sup>, Sabine Braat<sup>2</sup>, Anita Skandarajah<sup>3</sup>, Swee Wong<sup>4</sup>

<sup>1</sup>Gynaecology Research Group, Department of Obstetrics and Gynaecology, The University of Melbourne & Royal Women's Hospital, Parkville, VIC 3052

<sup>2</sup>Melbourne School of Population and Global Health and Melbourne Clinical and Translational Sciences Platform (MCATS), The University of Melbourne, Parkville, VIC 3052

<sup>3</sup>Breast Service, The University of Melbourne, Royal Women's Hospital, and Royal Melbourne Hospital, Parkville VIC 3052 <sup>4</sup>Pharmacy, Royal Women's Hospital, Parkville, VIC 3052

### Introduction

- **Changes to sexual well-being affect 85% of women after breast cancer**
- Sexual discomfort after breast cancer impairs quality of life and affects relationships
- Mechanism is unclear but loss of vaginal oestrogen affects vaginal secretions and microbiome
- Role of vulva is unclear – recent evidence that local anaesthesia to vulva reduces pain during intercourse
- Vaginal dryness contributes to discomfort and is increased after menopause
- Most postmenopausal women are sexually active
- Unlike vasomotor menopausal symptoms, which commonly resolve over time, vaginal dryness persists and may get worse
- Topical oestrogens are effective at relieving dryness and may address pain during sexual activity, but is avoided in breast cancer patients
- Topical testosterone and dehydroepiandrosterone (DHEA) may be effective but their safety after breast cancer has not been established
- Non-hormonal treatment alternatives are limited
- **Lubricants are widely used** by women to reduce discomfort during sexual activity and represent a market of \$208m per annum in the US
- Common lubricant bases:
  - Water – stabilized and thickened with hydrophilic substances (glycerine, cellulose glycols, carrageenan); readily evaporate
  - Silicone (polymerized siloxanes) – very low surface tension, form thin, gas-permeable, high-slip films easily on skin and mucous membranes; persistent
  - Oil – derived from petroleum or plants; persistent, not readily absorbed

**AIM: To compare the efficacy and acceptability of a silicone-based vaginal lubricant versus a water-based lubricant in breast cancer patients with symptomatic vaginal dryness**

Anonymous (2011) Chain Drug Rev; Committee on Practice, Bulletins-Gynecology (2012) Obstet Gynecol 119:666; Goetsch, Lim and Caughey (2015) J Clin Oncol 33:3394; Ussher, Perz, and Gilbert (2013) J Adv Nursing 69:327.

### Study Design

#### Inclusion criteria:

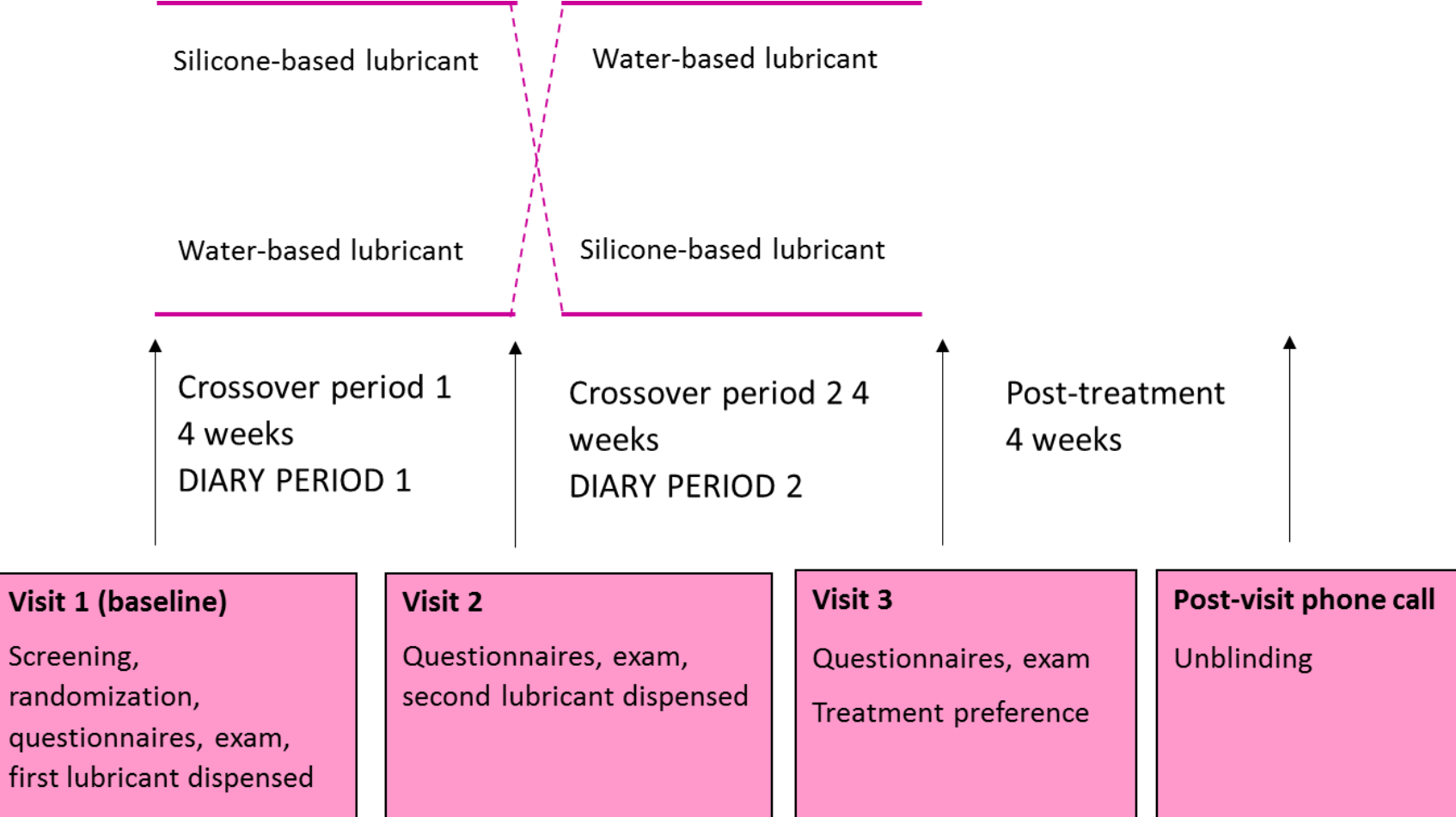
- History of breast cancer
- Sexually active and symptoms of vaginal dryness or dyspareunia
- Willing to be randomized and try both products
- Willing to complete daily sexual activity diary
- Normal Pap in last 2 years (or willing to have one) if retained uterus

#### Exclusion criteria:

- Systemic or vaginal oestrogens or tibolone in previous 6 weeks
- Current symptoms of vaginal infection
- Postmenopausal bleeding
- Allergy to water- or silicone-based lubricants
- Clinically significant anxiety or depression

#### Design and materials:

- Randomized AB/BA crossover design
- Silicone-based lubricant: Pjur (pjur group, Wasserbillig, Luxembourg)
- Water-based lubricant: Astroglide (BioFilm Inc., Vista, California)
- Double-blinded, identical packaging



### Measurements and Analysis

#### Primary outcomes

##### Efficacy: Total sexual discomfort

- Sexual Activity Questionnaire <sup>1</sup> Discomfort subscale (SAQ-D)
- Two items, each scored 0-3, summed to 0-6, higher worse
- Linear regression model including treatment sequence, participant nested within treatment sequence, treatment and period

##### Acceptability

- Investigator-designed item combining preference and plans for further use

#### Secondary outcomes

##### Vaginal dryness and pain during penetration (dyspareunia)

- Sexual Activity Questionnaire – SAQ-D individual items
- “During sexual relations, how frequently did you notice dryness of your vagina this month?”
- “Did you feel pain or discomfort during sexual penetration this month?”
- Post-hoc analysis, cumulative proportional odds models

##### Sexual pleasure

- Sexual Activity Questionnaire - Pleasure subscale (SAQ-P)
- Six items, past month, range 0-18, higher better
- Linear regression model including treatment sequence, participant nested within treatment sequence, treatment and period

##### Sexual habit

- Sexual Activity Questionnaire – Habit subscale (SAQ-H)
- One item, range 0-3, comparing past month sexual frequency to usual, higher more frequent
- Post-hoc analysis, cumulative proportional odds models

1. Thirlaway, Fallowfield and Cusick (1996) Qual Life Res 5:81.

### Measurements and Analysis, continued

#### Sexually-related personal distress

- Female Sexual Distress Scale – Revised <sup>1</sup> (FSDS-R)
- 13 items, range 0-52, higher worse
- Linear regression model including treatment sequence, participant nested within treatment sequence, treatment and period

1. Derogatis, Rosen, Leiblum et al. (2002) J Sex Mar Ther 28: 317.

### Results

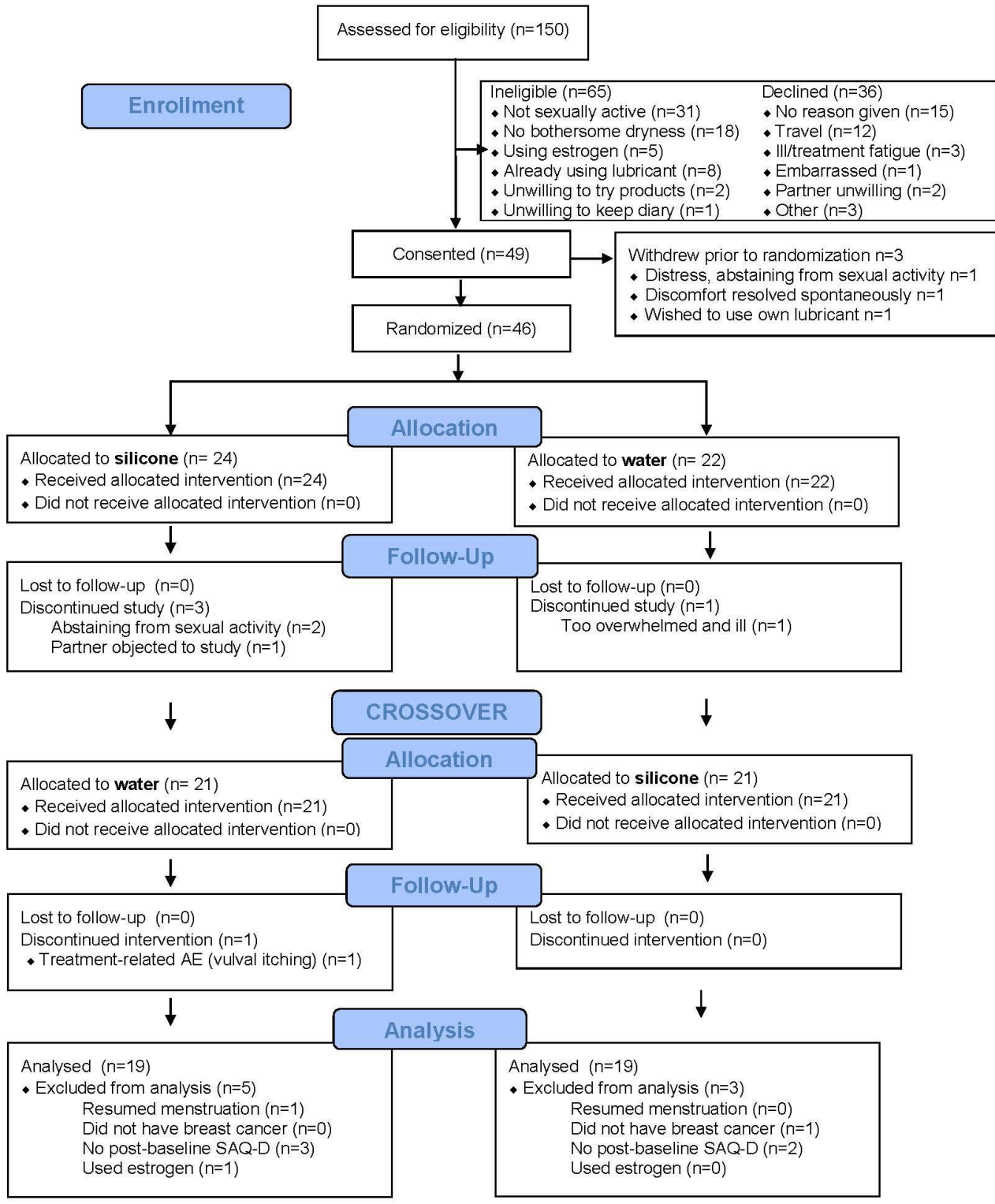


Figure 1. CONSORT diagram

- Nearly half of those ineligible could not be included because they were not sexually active



#### Randomised: 46 women

- Analysis set: 38 women
- Average age: 53.1y, SD 4.8
- All Caucasian
- All but 1 partnered
- Median 3 y since cancer diagnosis

#### Acceptability:

- 11 (33%) women would use silicone-based again but not water-based
- 5 (15%) women would use water-based again but not silicone-based
- 9 (27%) would use either again but preferred silicone-based
- 6 (18%) would use either but preferred water-based
- 1 (3%) would use either without preference
- 1 (3%) would use neither again
- 5 missing values

#### Efficacy

- Overall, there was no significant difference between water and silicone-based lubricants in reducing total discomfort due to sexual activity (Table 2)
- Sexually-related distress did not differ by lubricant type, and remained above twice the clinically significant cut-off score for both preparations (Table 2)
- Pain/discomfort during penetration (dyspareunia) improved significantly more during silicone lubricant use compared to the water-based product (Table 3)
- 88% (n=30) of participants still experienced clinically significant distress at the end of the study

Efficacy outcome measure	Water-based lubricant Mean (SD)	Silicone-based lubricant Mean (SD)	Estimated mean difference Water minus silicone (95% CI)	p
Total sexual discomfort	4.2 (1.9)	3.5 (1.8)	0.7 (0.0, 1.4)	0.06
Sexual pleasure	10.1 (4.9)	11.3 (3.8)	-1.0 (-2.5, 0.4)	0.2
Sexual distress	24.9 (13.6)	22.7 (14.3)	1.9 (-1.1, 4.9)	0.2

Table 1. Differences between water- and silicone-based lubricants in total sexual discomfort (primary efficacy outcome), sexual pleasure and sexually-related distress (secondary efficacy outcomes).

Efficacy outcome measure	Score change from water-based to silicone-based n (%)					Odds ratio (95% CI)	p
	Much better	Better	Same	Worse	Much worse		
Dyspareunia	2 (5.9)	12 (35.3)	16 (47.1)	4 (11.8)	0 (0)	5.4 (1.3, 22.1)	0.02
Dryness	2 (5.9)	10 (29.4)	14 (41.1)	8 (23.6)	0 (0)	1.9 (0.6, 6.8)	0.3
Sexual habit	0 (0)	16 (47.1)	11 (32.4)	7 (20.6)	0 (0)	1.1 (0.3, 3.9)	0.9

Table 2. Changes from water-based to silicone-based lubricant in dyspareunia and dryness (individual components of total sexual discomfort score) and sexual habit.

### Conclusions

- **Pain during penetration was lower after use of silicone-based** than water-based lubricant but total sexual discomfort did not differ by lubricant type
- **Sexual distress remains very high in this population**

### Acknowledgments

- Our thanks to the participants in the study, to study coordinator Soula Krejany, to study nurses Lee Ann Mahoney, Kathrine Allardice, and Lorraine Thomason, to research pharmacists Lisa Wolke and Christine Gilmartin and to the MSAC Clinic and RWH Pharmacy staff.
- The study was partially supported by an educational grant from pjur, Luxembourg, which included bulk supply of both water- and silicone-based lubricants but not packaging or dispensing. The company had no input into the study design, data collection, analysis of findings, interpretation of results or writing of this abstract or any related manuscripts.