

Intravaginal Practices by Phase II Carraguard™ Trial Participants in South Africa

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Definition of intravaginal practices

Inserting something into the vagina...

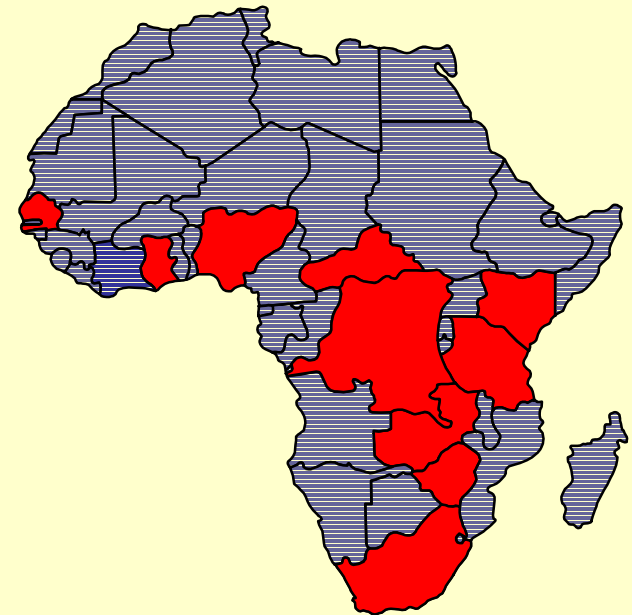
- To clean inside Π
- To wipe / dry Π
- To tighten or warm during sex Π
- To lubricate during sex (Π)
- To treat infections
- To control menstrual flow
- To prevent pregnancy / STIs
- To induce abortion

How widespread are these practices?

Cleansing, drying and tightening practices reported:

- **11 countries in Africa**
- **Indonesia, Thailand, Qatar, Dominican Republic, Haiti and the U.S.**

- Source: Brown et al., 1999



Relationship to HIV and other STIs

Three potential mechanisms:

- **Dry or irritate cervical and vaginal mucosa**
- **Interfere with healthy vaginal flora**
- **Interfere with acceptability and efficacy of barrier methods and microbicides**

Methodology

Context: Randomized, placebo-controlled, double-masked Phase II Carraguard™ trial

Sites: Ga-Rankuwa & Gugulethu, South Africa

Sample: 200 out of 400 participants

Population: HIV- women from clinics & community

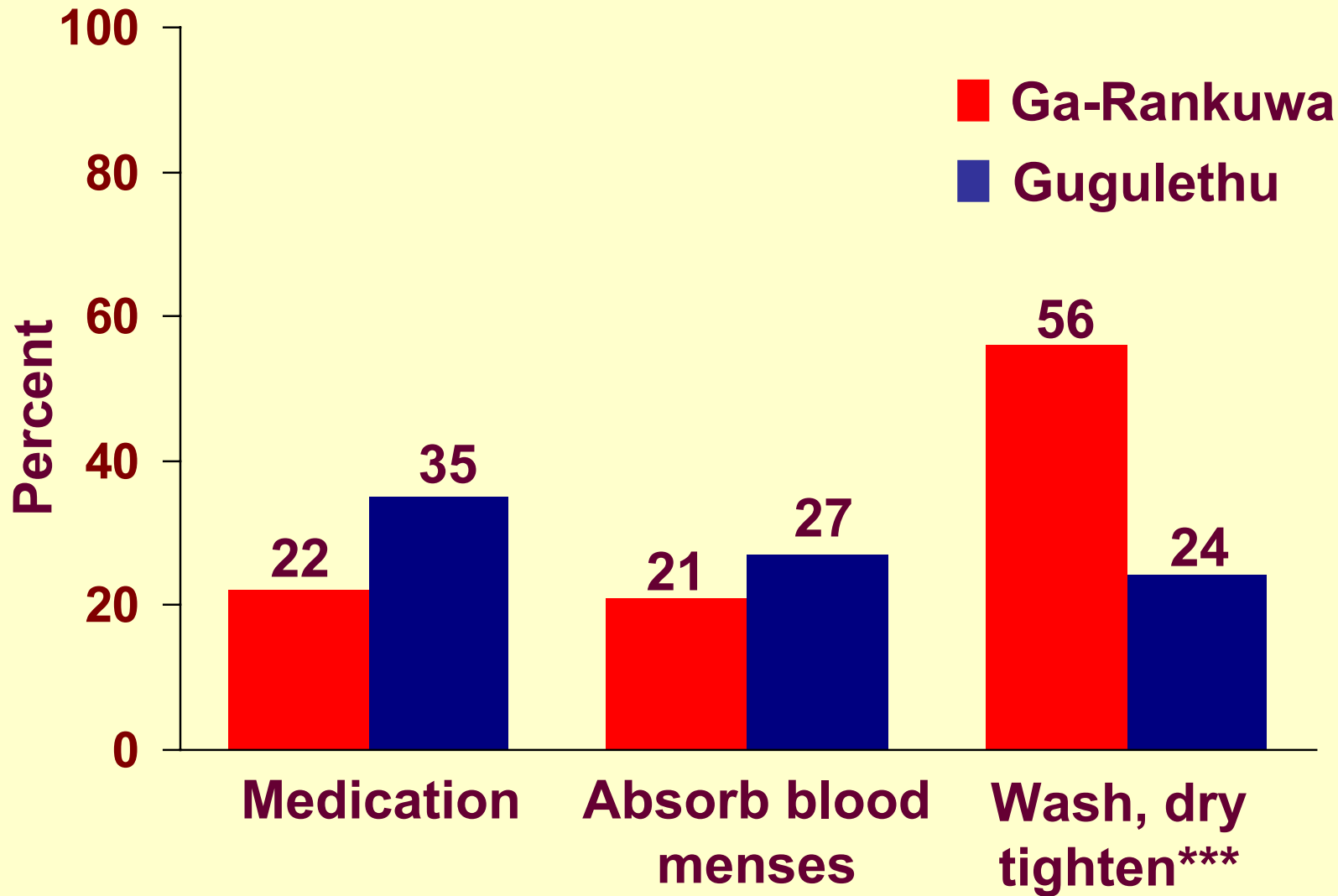
Data collection: Interviewer-administered in Tswana or Xhosa, August – December, 2001

Characteristics and behaviors by site

	Ga-Rankuwa	Gugulethu
Mean age	26.9	29.0*
Mean parity	1.2	1.5
Mean yrs educ	9.4	7.9**
Married/steady part. (%)	83	90
FP use at screening (%)		
None/withdrawal	23	9**
Hormonal	69	68
Male condom	1	6
Long-term	7	17*
Anal sex last yr (%)	2	4
Oral sex last yr (%)	9	7

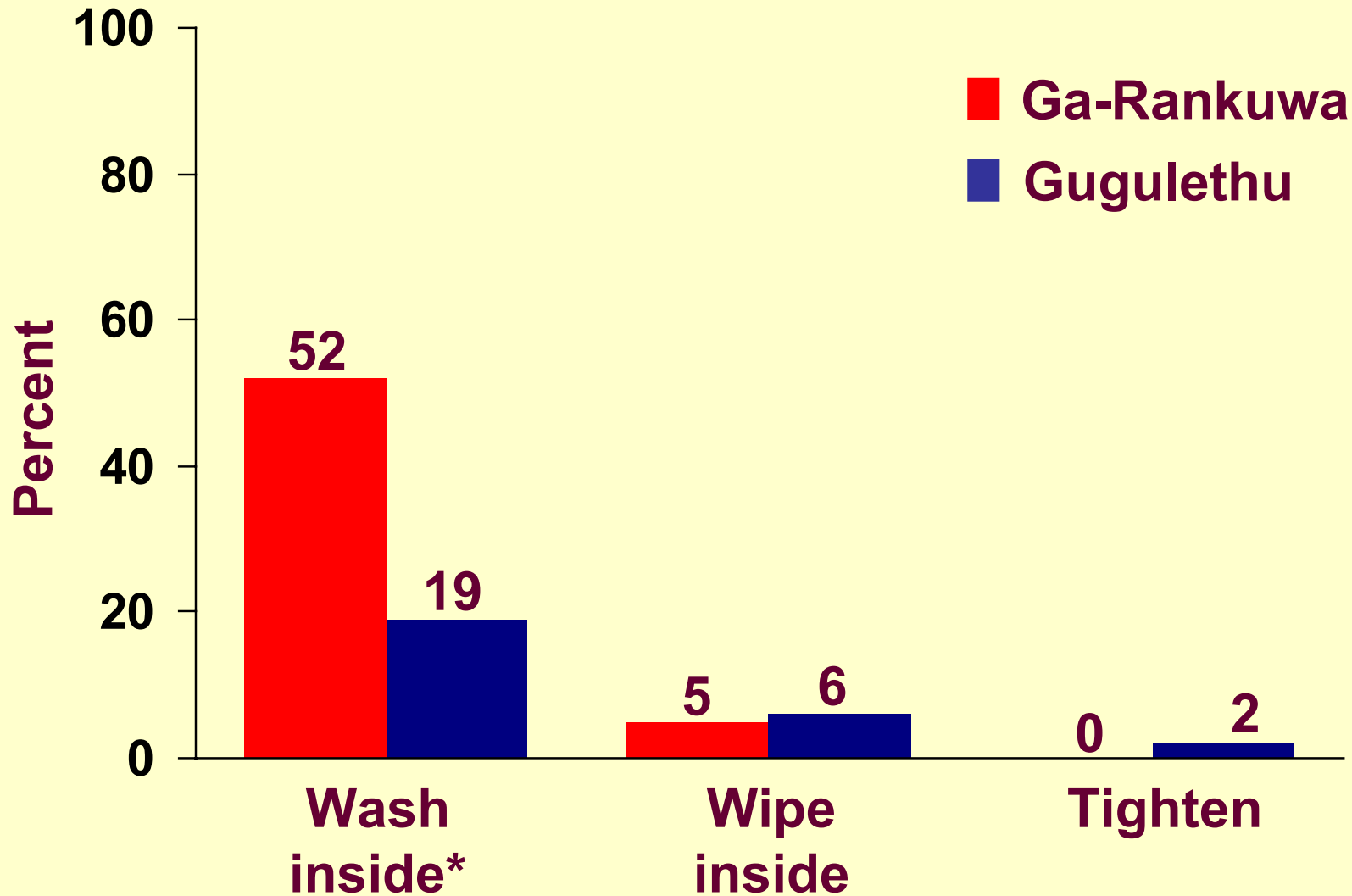
Source: Phase II screening data (n=200), 2001; * p<.05, ** p <.01

Reporting of ever practice by site



Source: Feasibility survey (n=200), 2001; * p<.05, ** p <.01

Reporting of ever practice by site



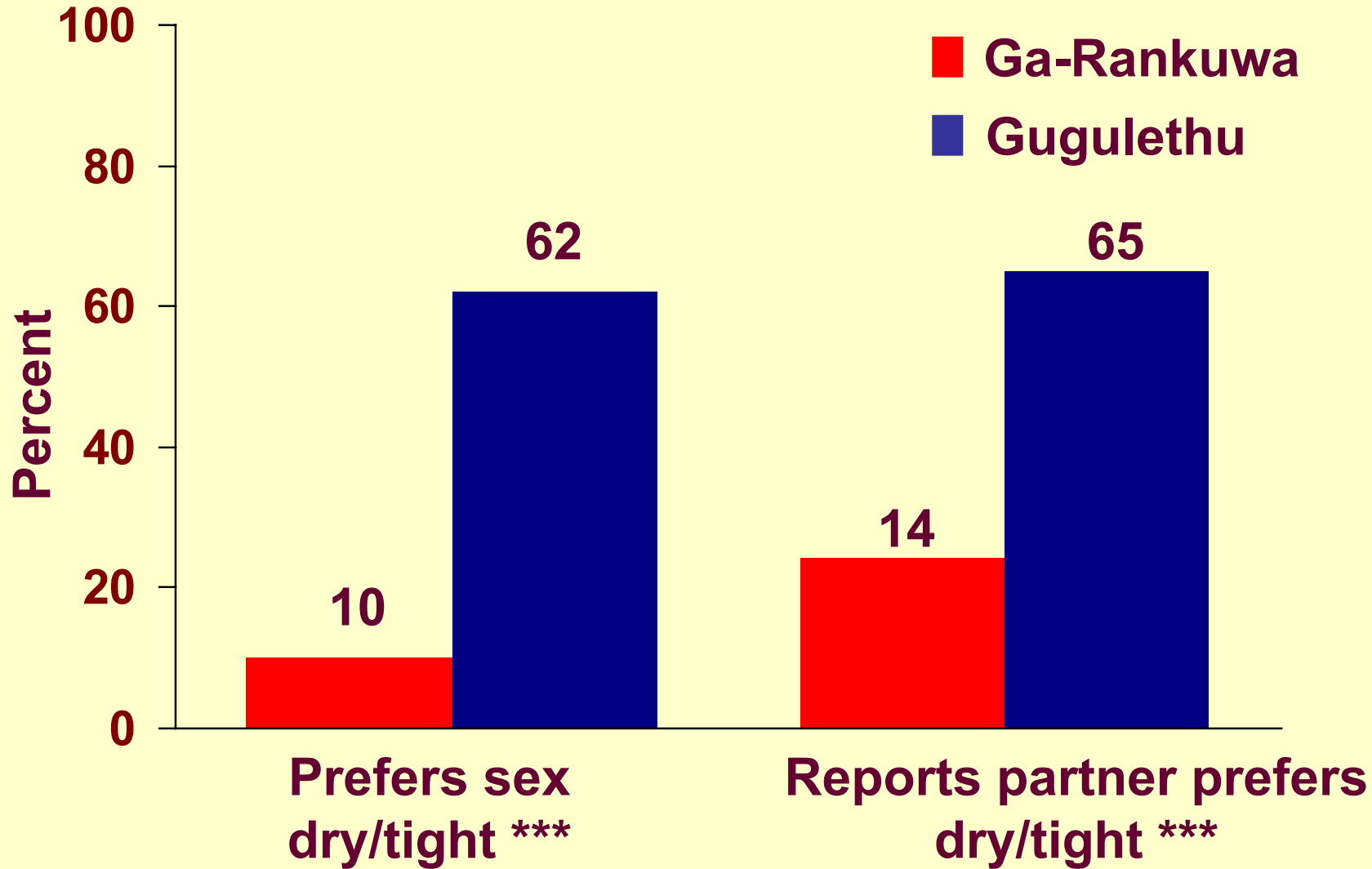
Source: Feasibility survey (n=200), 2001; * p<.05, *** p <.001

Reporting of practice during the trial

	Ga-Rankuwa	Gugulethu
Mean months using gel	8.5	9.5**
Wash outside (%)	97	97
Insert medication (%)	10	23*
Absorb blood during mens. (%)	18	16
Wash inside (%)	30	13**
Dry inside (%)	4	2
Tighten (%)	0	2
Insert soon before, after, during gel use (%)	2	1

Source: Feasibility survey (n=200), 2001; * p<.05, ** p <.01

Sexual lubrication preferences by site



Source: Feasibility survey (n=200), 2001; * p<.05, ** p <.01

Determinants: Ever practice, prefer dry

Determinant	Odds Ratio	
	Ever practice	Prefer dry/tight
Ga-Rankuwa	3.9 ***	0.1 ***
Gugulethu (r)	1.0	1.0
FP at screening:		
None (r)	1.0	1.0
Hormonal method	1.4	2.4
Male condom	2.1	1.6
Long-term method	0.2 *	2.1
Age	1.0	1.0
Parity	1.4	0.9
Education	1.0	0.8 *

Source: Feasibility survey (n=197), 2001; * p<.05, *** p <.001

Qualitative lubrication study

- **Significant variability around lubrication by age, gender, region, and ethnic group**
- **Perceptions of sexual hygiene and cleanliness seem to have widespread importance**
- **There may be consequences for women if the “right amount” of lubrication is not achieved during sex**

Source: Braunstein & van de Wijgert, Abstract #C132

Conclusion

- **Intravaginal practices are common, especially washing inside the vagina**
- **Significant regional differences in terms of intravaginal practices and preferences for lubrication during sex**
- **Preference for dry sex does not necessarily translate into inserting something into the vagina (may relate to foreplay and “readiness”)**

Conclusion: Microbicides Research

- **Phase III effectiveness trials must explicitly instruct women not to insert anything between insertion of gel and sexual intercourse**
- **More research is needed on intravaginal practices and lubrication preferences for relationship to efficacy and acceptability of products**
- **More research is needed on couples' communication and issues around “readiness” for sex**

Related posters

- **Feasibility Survey
Phase III Protocol Issues
Abstract # B-124**
- **Qualitative Lubrication Study
Abstract # C-132**