

BACKGROUND

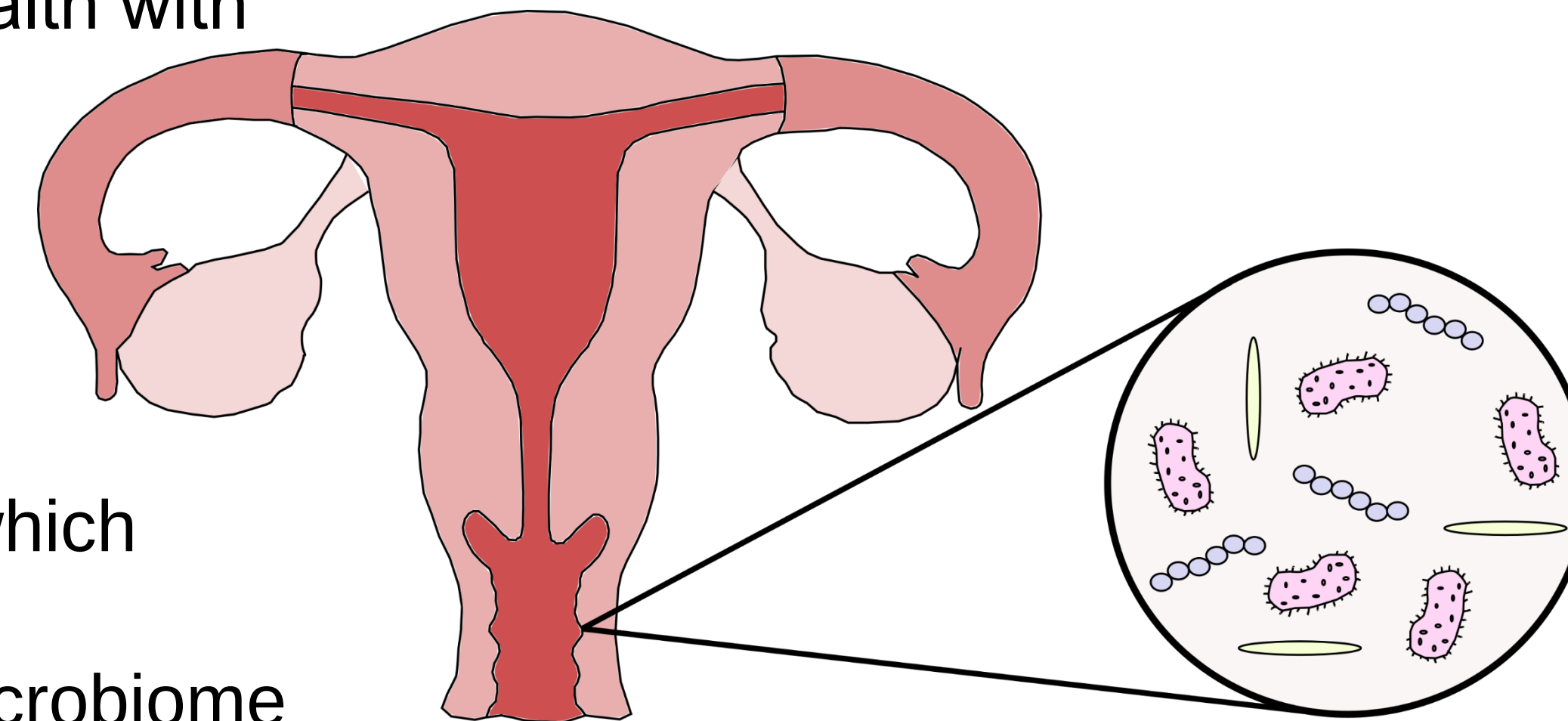
The vaginal microbiome plays a key role in women's reproductive health with impacts on -

- Fertility
- Recurrent miscarriage
- Preterm birth
- Sexually transmitted infections

Typically the vaginal microbiome is dominated by lactobacillus spp. which maintains a healthy microenvironment.

Femoflor-16 rtPCR detection kit has enabled quick analysis of the microbiome with diagnosis of dysbiosis based on detection of a variety of microorganisms relevant to the microbiome.

Fear and embarrassment related to physicians taking a traditional vaginal swab using a speculum results in many missed appointments in the UK and recruitment challenges into vaginal microbiota research studies.



AIM

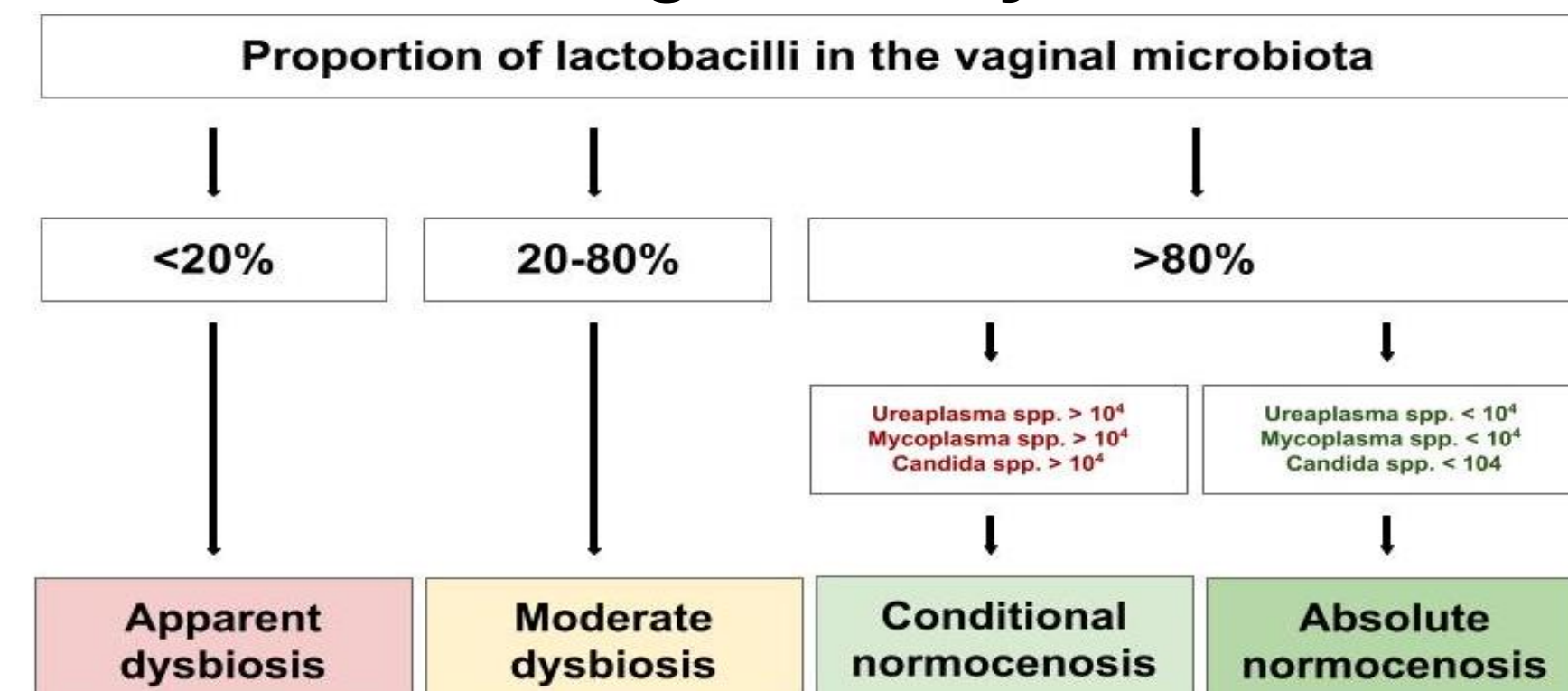
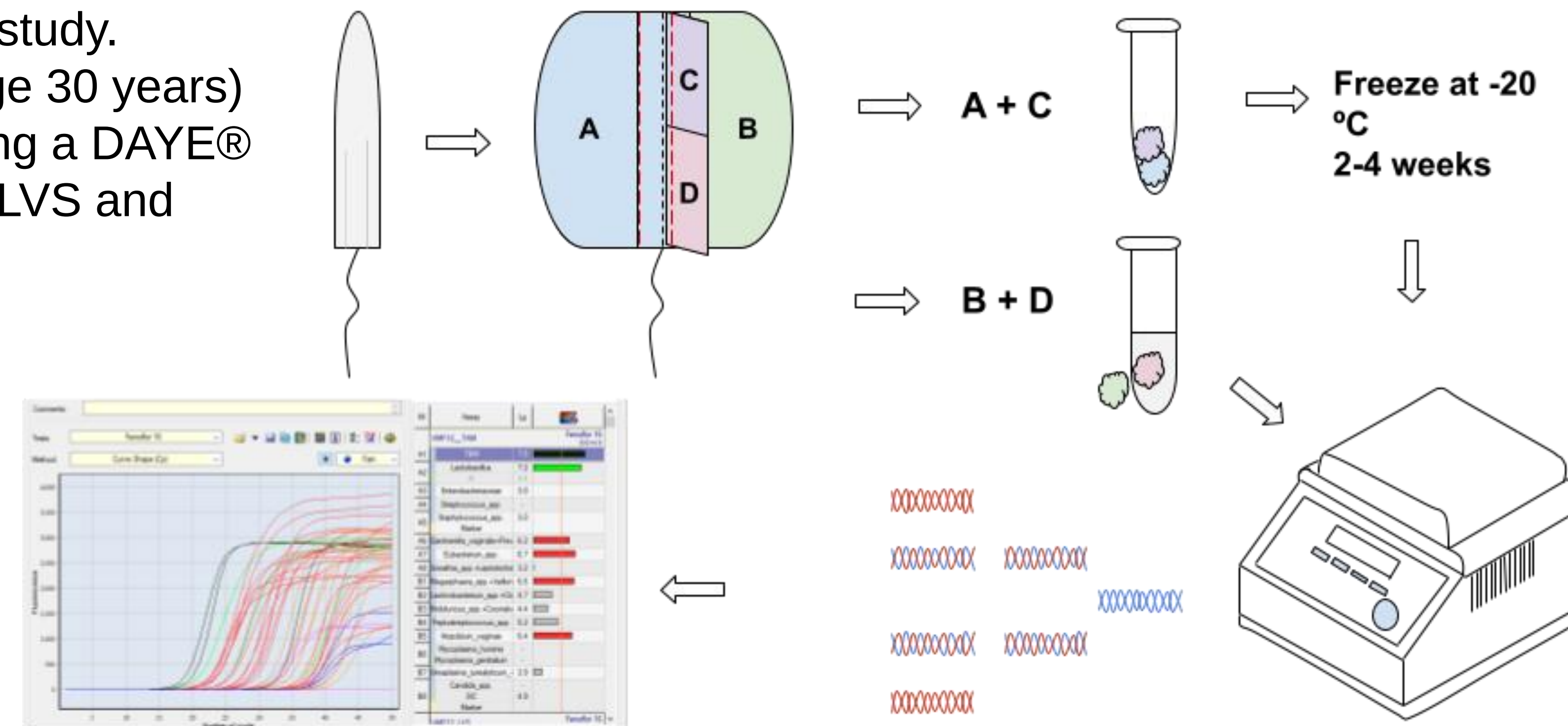
- Determine if menstrual tampons are an acceptable and comparable method to lower vaginal swabs (LVS) for analysing the vaginal microbiome in non-pregnant women and if a period of freezing alters the results

METHODS

Prospective, cross-sectional observational study.

Twenty-one healthy volunteers (average age 30 years) recruited over 6 weeks consented to wearing a DAYE® menstrual tampon for 20 minutes, taking 2 LVS and completing an acceptability questionnaire.

Criteria for diagnosis by FEMOFLO



RESULTS

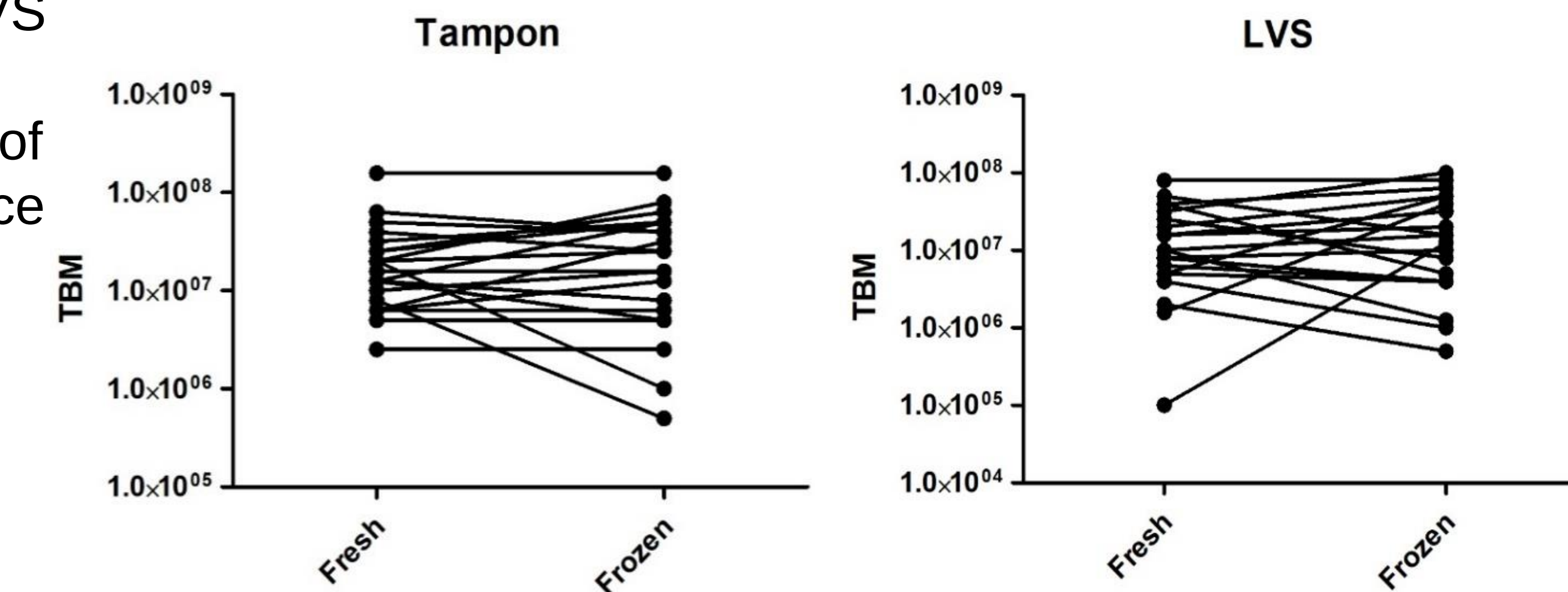
Of the 84 samples, four had insufficient material for analysis (2 fresh LVS, 1 frozen LVS and 1 frozen tampon).

Femoflor algorithm gave identical vaginal microbiota characterisation between fresh tampons and fresh LVS in 68.4% (13/19).

92% (12/13) samples with >80% relative abundance of lactobacillus in LVS also had >80% relative abundance in the tampon.

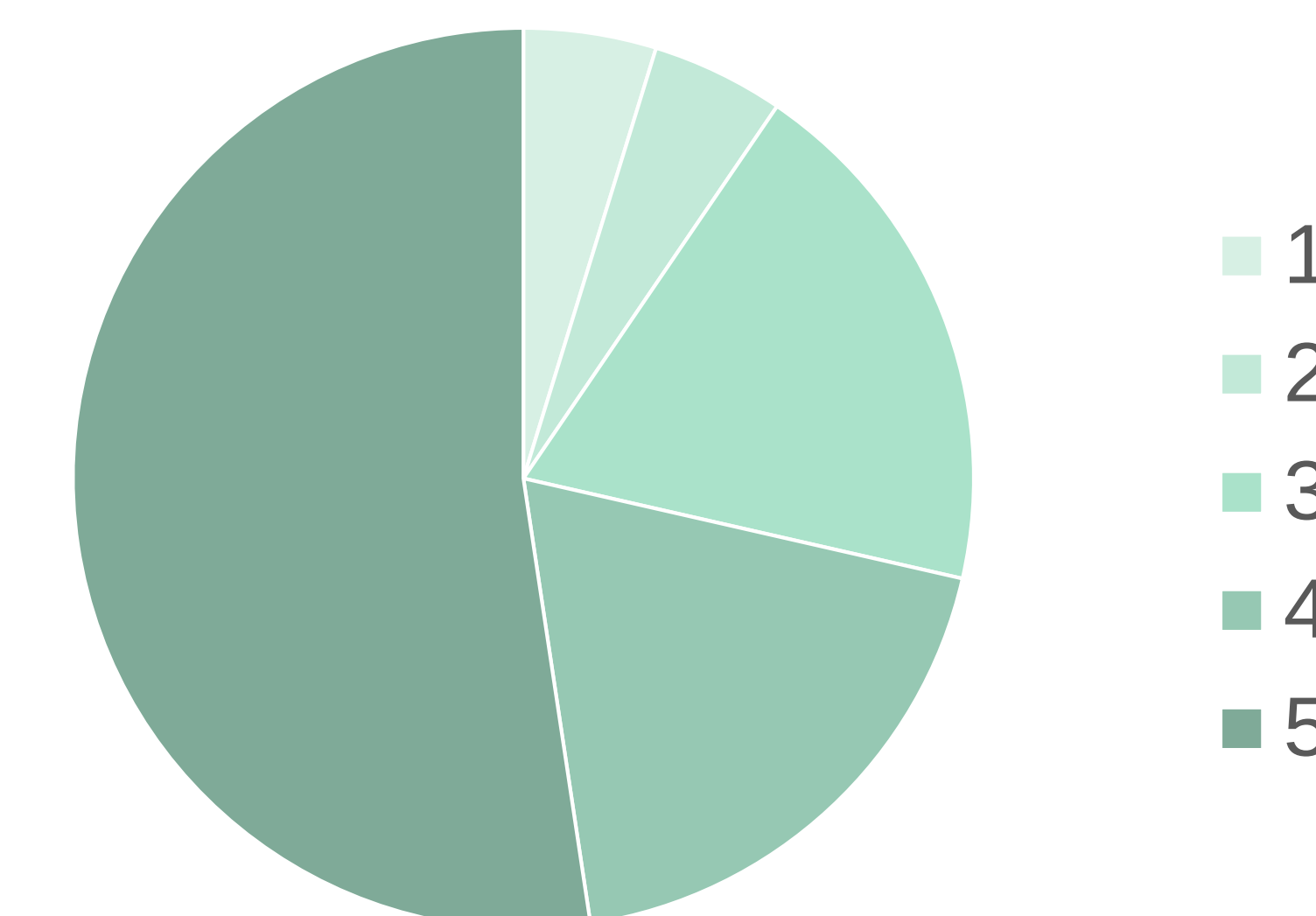
More discrepancy was seen between samples within the 20-80% and <20% relative abundance groups of lactobacillus in the LVS with 50% and 75% different classifications respectively.

Importantly, only one case showed an LVS with lactobacillus >80% (normal) and a tampon with non-dominance of lactobacillus (<80%, dysbiosis).

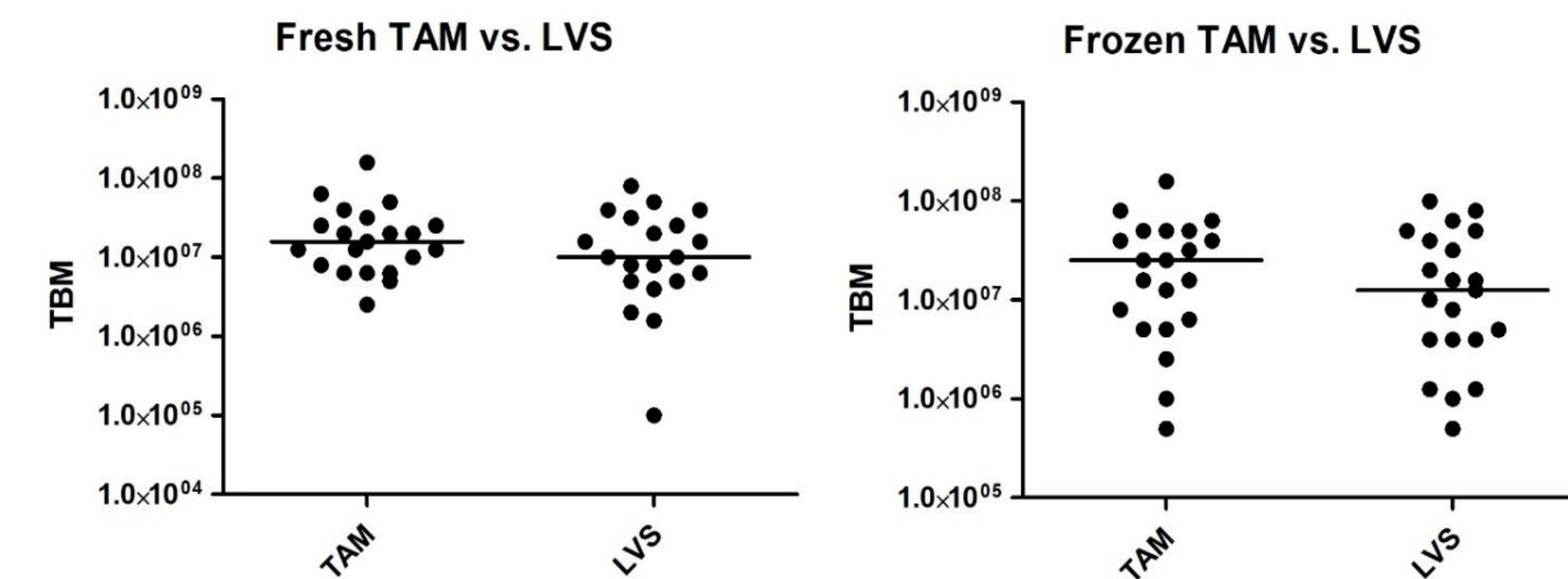


Before and after plot illustrating total bacterial mass in immediately processed samples versus frozen samples

Tampon acceptability



90.5% of volunteers highly rated using tampons (≥3/5 on Likert scale), with 52.4% rating tampon-use at 5/5. All participants stated they would be happy to provide a tampon sample for clinical/research testing in the future.



Mean total bacterial mass was higher in the tampon when comparing fresh tampon vs. fresh LVS and frozen tampon vs. frozen LVS.

CONCLUSIONS and RECOMMENDATIONS

Self-collected tampons are suitable, well accepted biospecimen collection devices that may reduce barriers posed due to embarrassment, improve attendance in genitourinary medicine clinics and encourage participation in vaginal microbiota research. Freezing samples before batch processing reduces time and costs. A large study is necessary to ensure reproducibility and acceptability to the patient population.