Is Glans swab appropriate for diagnosis of *C. trachomatis* infection in asymptomatic men?

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May 25-27, 2011, Jurmala, Latvia

Baltic Beach hotel

NAAT performance

- NAAT : highly sensitive and specific
- Allows detection in specimens obtained by non-invasive means

Why self-collected specimens?

- Non-invasive
- Used for routine screening
- Collected in non-clinic settings
- Swabs versus urine?
  - In women, self collected vaginal swab > urine
  - Can be send by post
  - Better processing than urine

What are the specific problems related to urine?

Voiding interval before testing urine?

The significance of voiding interval before testing urine samples for *Chlamydia trachomatis* in men

K Manavi, H Young

Sex Transm Infect 2006;**82**:34–36. doi: 10.1136/sti.2005.015354

See end of article for

Int J STD AIDS. 2009 Nov;20(11):752-3.

Shortening the voiding interval for men having chlamydia nucleic acid amplification tests.

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What are the problems related to urine?

Volume effect?

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0095-1137/03/$08.00+0 DOI: 10.1128/JCM.41.10.4842–4843.2003

Volume Effect on Sensitivity of Nucleic Acid Amplification Tests for Detection of *Chlamydia trachomatis* in Urine Specimens from Females

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Nucleic acid amplification tests (NAATs) for the detection of *Chlamydia trachomatis* are routinely used on first-catch urine (FCU) specimens. We analyzed data from a head-to-head comparison of NAATs on female FCU specimens and found that the volume of urine collected could affect test performance.

What are the problems related to urine?

- Processing for PCR
  - Centrifugation?
  - Frezzing or not to eliminate inhibitors?
  - Volume to PCR test?

Evaluation of self-collected glans swabs

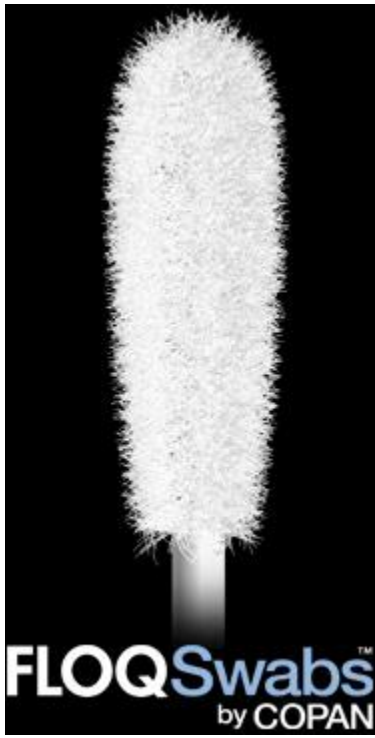
- Objectives
  - To compare the sensitivity of the GS to that of the FCU
  - To determine the feasibility as an alternative to FVU

- Methods
  - Men (heterosexual and MSM) screening center in Bordeaux, France
  - Inclusion criteria : to be asymptomatic
    to be < 30 years old + one risk factor
  - Exclusion criteria : urination within the previous 2 hours
    use of AB in the past 5 weeks

Evaluation of self-collected glans swabs

- Sample collection
  - each man self-collected 2 specimens
    - Firstly , a glans swab using a flocked swab

    - Secondly, a first void urine



A sample instruction sheet was given to advise men on how to take their own samples. The nurse gave an oral explanation taking her thumb as example

Evaluation of self-collected glans swabs

- Laboratory method
  - Method 1 : swabs were discharged into M4RT medium (500µl)
  - Method 2 (pooling strategy) : swabs were discharged into urine (500µl)

  Extraction: MagNaPure + LC DNA isolation kit (Roche)

  200µl of swab medium

  urine or urine +swab, centrifuged and pellet in 200µl of lysis buffer

  Amplification : Cobas TaqMan 48

Evaluation of self-collected glans swabs

- Discrepant analysis

  - re-test by using Cobas TM 48 and in house omp1 PCR every couples of specimens with only one positive PCR result

  - a patient was considered as infected

    when both samples were positive

    or when one sample was positive by both PCR tests

Evaluation of self-collected glans swabs

- Results
  - Method 1 total agreement 325/344 94.45%
    positive agreement 15/34 44%

	Specimens		Status of infection	
	FCU	GS	Infected N=27	Non infected N= 317
	+	+	15	0
	+/+	-/-	9	0
	+/-	-/-	0	3
	-/-	+/+	3	0
	-/-	+/-	0	4
	-	-	0	310
Sensitivity	24/27 **89%**	18/27 **67%**		

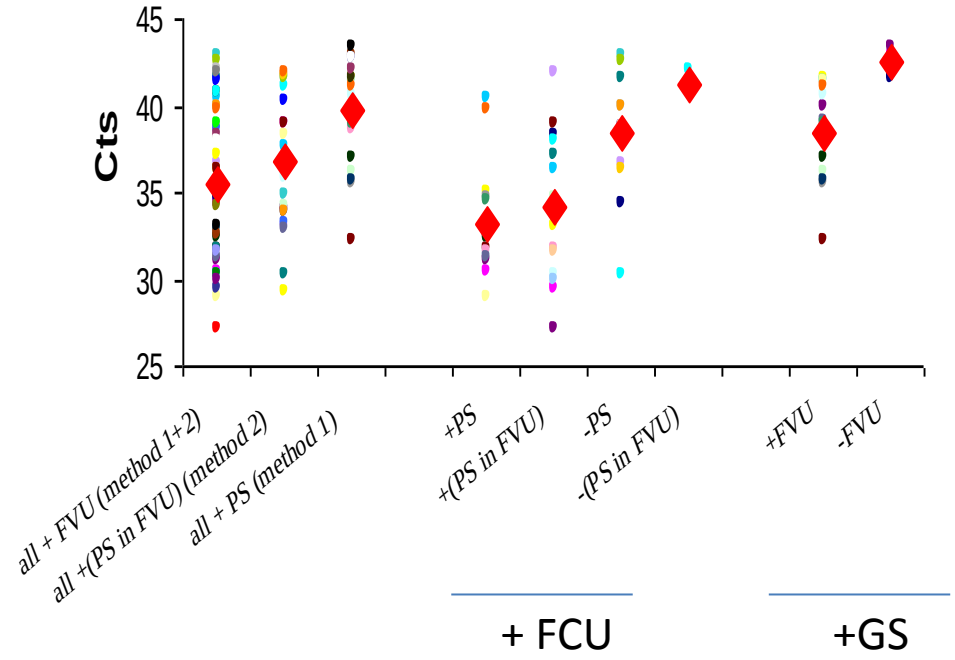
Evaluation of self-collected glans swabs

- Results
  - Method 2 total agreement 249/259 96.14%
    positive agreement 17/27 62.9%

	Specimens		**Status of infection**	
	FCU	GS + FVU	Infected N=19	Non infected N= 232
	+	+	17	0
	+/+	-/+	1	0
	+/-	-/-	0	3
	-/-	+/+	1	0
	-/-	+/-	0	5
	-	-	0	232
Sensitivity	18/19 **94.7%**	18/19 **94.7%**		

Evaluation of self-collected glans swabs

Comparison of *C. trachomatis* load in each specimen



Conclusion

- Higher sensitivity for FVU
- Pooling strategy doesn't improve the sensitivity
- In asymptomatic men, the number of bacteria is often very low and could explain:

- The discrepancies between both specimens
- The low sensitivity of penile swab given that patient could not perform the appropriate collection technique
- The non reproducibility of results and the number of results classified as false positive
- These results suggest the self-collected glans swab may not be useful for *C. trachomatis* testing

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0095-1137/09/$08.00+0 doi:10.1128/JCM.01165-09

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Glans Swabs Are Not Appropriate Specimens for Diagnosis of *Chlamydia trachomatis* Infection in Asymptomatic Men[▽]

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0095-1137/09/$08.00+0 doi:10.1128/JCM.02269-08

Evaluation of Self-Collected Glans and Rectal Swabs from Men Who Have Sex with Men for Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Use of Nucleic Acid Amplification Tests[▽]

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Sex Transm Dis. 2008 Dec;35(12):999-1001.

Comparison of penile skin swab with intra-urethral swab and first void urine for polymerase chain reaction-based diagnosis of Chlamydia trachomatis urethritis in male patients.

Pittaras TE, Papaparaskevas J, Houhoula DP, Legakis NJ, Frangouli E, Katsambas A, Tsakris A, Papadogeorgakis H.

Department of Microbiology, Medical School, University of Athens, Athens, Greece.

Moncada study

- Specimen collection
  - A self-collected glans swab
    - Method 1 : roll swab across opening of penis 3x
    - Method 2 : insert swab ¼ inch into urethra, rotate 1x
  - FCU
- Sensitivity (907 men)

Test	site	method1	method2
SDA	swab	56.3	60.7
AC2	swab	59.4	67.9
AC2	FCU	93.8	82.1

Pittaras study

- Specimen collection
  - Clinician collected samples
    - Penile skin swab (PSS)
    - Intra urethral swab (IUS)
  - FCU
- Sensitivity

Test	site	%
amplicor	PSS	78.7
	IUS	89.4
	FCU	89.4

-Urine remains the sample of choice to detect *C.trachomatis* infection in men
- a solution may exist to transport urine safety