Use of the Diaphragm for the Prevention of Cervical STD

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The diaphragm: a brief history
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- Described by Dr. Wilde in 1838 following the vulcanization of rubber
- Use spread rapidly in Europe
- In the early 1900’s Margaret Sanger and Emma Goldman saw a variety of diaphragms used in Europe
The diaphragm: a brief history

- Introduced to US in 1916 by Sanger in her Brooklyn clinic. Clinic was closed after 10 days by NYC Vice Squad.

- Deemed guilty of “maintaining a public nuisance”, Sanger arrested, convicted and jailed for 30 days.

- Sanger re-opened clinic upon release from jail.
The diaphragm: a brief history

- In 1925 Sanger’s husband established the first US diaphragm manufacturer
- Initial popularity then progressive decline in use; women shift to hormonal contraception.
- Recent increased interest in possible diaphragm use for STD/HIV prevention.
Diaphragm use for STD prevention

- Biologic plausibility
- Observational studies in humans
- Need for adjunctive microbicide:
  - data from contraceptive efficacy trials
- Potentially deleterious effects of the diaphragm
Normal cervix
Normal cervical epithelium
Columnar epithelium
OR for Chlamydia: Diaphragm vs. no method

McCormick ‘85
Magder ‘88
Rosenberg ‘92
Park ‘95
Cramer ‘87
OR for Gonorrhea: Diaphragm vs. no method

Berger ’75 *
Austin ‘84
Quinn ’85 *
Rosenberg ‘92

Graph showing

0 1 2
OR for PID:
Diaphragm vs. no method

Kelaghan ‘82

Wolner-Hanssen ‘90

0 1 2
OR for Neoplasia: Diaphragm use vs. never use

Hildesheim ‘90
- < 5 yrs
- 5 + yrs

Becker ‘94
- Ever
- Current
- Past
Source of protection

• Women who use the diaphragm are, in general, less likely to have:
  – Chlamydia infection
  – Gonorrhea
  – PID
  – HPV-associated cervical dysplasia

• Does this mean that the diaphragm protects against these infections?
Possible confounding by sexual behavior

- Studies of the diaphragm do not present high level evidence. All are:
  - Level IIB: cohort or case-control studies;
  - Level III: descriptive studies.

- No randomized clinical trials (Level 1) to date.

- Lower risk of non-cervical STD among diaphragm users suggests differences in behavior.
  - Trichomonas: OR = .29 [.15, .58]
Will use of the diaphragm alone be sufficient for STD Prevention?

Insights from the contraceptive literature about the role of adjunctive chemical barriers
Typical 12-month pregnancy rate
diaphragm +/- spermicide

Ferreira ‘93
+ 
–

Bounds ‘95

Typical
+ 
–

Consistent
+ 
–

0 10 20 30 40
Pregnancies/100 woman
Typical 6-month pregnancy rate barrier +/- spermicide

- Smith ‘95
- Mauck ‘97
+ Lea’s
- Shield

Pregnancies/100 woman
Potentially deleterious effects of the diaphragm

Urinary Tract Infection
Toxic Shock Syndrome
OR/RR for UTI: Diaphragm vs. oral contraceptives

Finn ‘85
Hooton ‘96
d/wk 1
   2
   3-7
Scholes ‘00
Spermicide
Diaphragm
RR for Bacteriuria: Diaphragm (d/wk)

Hooton ‘00

- Spermicide alone
- Diaphragm

0 1 2 3 4 5
Toxic Shock Syndrome

- Case reports of toxic shock syndrome after prolonged & short-term diaphragm use.

- …cases of nonmenstrual TSS among diaphragm users have been reported previously…. to date, 18 definite and five probable cases associated with diaphragm use have been reported to CDC. (MMWR, 1984)
Diaphragm Use for STD Prevention

- Ongoing/Planned Trials (CDC/ USAID/ CONRAD)
  - Acceptability
  - Efficacy for CT/GC re-infection
  - Safety with microbicides
  - Acceptability / Use pattern in CSW
  - Safety of silicone vs. latex diaphragm?
Take-Home Messages

• Diaphragms cover the columnar epithelium of the cervix, site of chlamydial & gonococcal infections

• Women who use the diaphragm plus a spermicide (N-9) were less likely to have
  – Chlamydia infection
  – Gonorrhea
  – PID
  – HPV-associated cervical dysplasia
Take-Home Messages

• The evidence for protection is not strong and the possibility of confounding by sexual behavior has not been ruled out.

• Although not statistically significant, contraceptive studies suggest that adjunctive microbicide use may increase efficacy.
Take-Home Messages

• Diaphragm is associated with increased risk of symptomatic UTI, recurrent UTI and asymptomatic bacteriuria. Part of risk may be attributable to spermicide.

• Diaphragm use associated with toxic shock syndrome; absolute risk is low. Need to consider implications of prolonged use, poor cleaning.
Take-Home Messages

Sometimes doing the right thing takes great courage.

Margaret Sanger