

**STANDARD TREATMENT
GUIDELINES
MEDICINE
(NON RESPIRATORY
INFECTIOUS MEDICAL CONDITIONS)**

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NAME OF CONDITION: Endocervicitis (mucopurulent cervicitis or MPC)

I. WHEN TO SUSPECT/ RECOGNIZE?

Case definition

An inflammation of the cervical mucosa characterized by two major diagnostic signs.

- Purulent or mucopurulent endocervical exudate (mucopurulent cervicitis)
- Sustained endocervical bleeding easily induced by gentle passage of a cotton swab through the cervical os.

Either or both signs might be present.

Introduction:

Symptoms

- Asymptomatic in majority
- Abnormal vaginal discharge in some
- Post coital and intermenstrual vaginal bleed

Causative organisms:

- C. trachomatis
- N. gonorrhoeae
- Mycoplasma genitalium

II. INCIDENCE OF THE CONDITION IN OUR COUNTRY

No institutional data available in the Indian scenario.

III. DIFFERENTIAL DIAGNOSIS

- Cervical ectopy (seen in adolescents)
- Ectropion (patulous parous cervix)
- Ectocervicitis caused by HSV, T. vaginalis, CMV, C. albicans
- Endocervical inflammation associated with oral contraceptive use

IV. PREVENTION AND COUNSELING

General measures as applicable to all patients with suspected STIs

- Educate and counsel patient and sex partner(s) regarding RTIs/STIs, genital cancers, safer sex practices and importance of taking complete treatment.
- Treat partner(s) for the suspected organisms.
- Advise sexual abstinence during the course of treatment to minimize transmission.
- Promote the use of barrier contraception like condoms, educate about correct and consistent use.
- Refer for voluntary counseling and testing for HIV, Syphilis and Hepatitis B.
- Consider immunization against Hepatitis B.
- Schedule return visit after 7 days to ensure treatment compliance as well as to see reports of tests done.
- If symptoms persist, assess whether it is due to treatment failure or reinfection and advise prompt referral.

V. OPTIMAL DIAGNOSTIC CRITERIA, INVESTIGATIONS, TREATMENT & REFERRAL CRITERIA

***Situation 1: At Secondary Hospital/ Non-Metro situation: Optimal Standards of Treatment in Situations where technology and resources are limited**

Clinical Diagnosis:

Based on

- History of abnormal vaginal discharge, urinary burning or frequency, dysmenorrhoea, menorrhagia, irregular menstrual cycles.
- Speculum examination showing signs of cervical infection like yellowish discharge, redness with swelling, easy bleeding on probing cervix, cervical erosion to be assessed.
- Swab test: yellow colour of endocervical discharge visualized on a white swab
- Bimanual pelvic examination: fornicial or cervical motion tenderness suggests PID

Investigations:

- Gram's stain of endocervical mucus: to document cervicitis and look for presence of GNID
- Cervical Cytopathology: PAP smear can demonstrate characteristic cellularity.

Treatment:

Provide presumptive therapy for cervicitis (not to await the results of diagnostic tests)

Treatment for cervical infection (chlamydia and gonorrhoea)

- Tab cefixime 400 mg orally, single dose
- Plus
- Tab Azithromycin 1 gram, 1 hour before lunch. (If vomiting within 1 hour, give antiemetic and repeat)

Alternative regimes

- Inj Ceftriaxone 250 mg im stat
- Plus
- Tab Doxycycline 100 mg orally twice a day for 7 days

If Vaginitis also present

- treat for both vaginitis and cervicitis (refer to guidelines)
- Trichomoniasis and BV should be treated if detected

Other measures to be advised

- Instruct client to avoid douching
- Advise sexual abstinence during the course of treatment

Follow-Up

- Followup after one week
- Repeat testing of all women with chlamydia regardless of whether their sex partners were treated as there is high risk of reinfection

Specific guidelines for partner management

- Treatment as for urethritis (refer to relevant guidelines)
- Provide condoms, educate about correct and consistent use

- Schedule return visit after 7 days

Special situations

- Pregnancy, diabetes, HIV may also be influencing factors and should be considered in recurrent infections

Management in pregnant women

- Per speculum examination
- In women with persistent symptoms attributable to cervicitis, refer to gynaecologist

HIV Infection

- same treatment regimen as those who are HIV negative

Recurrent and Persistent Cervicitis

- Reevaluate for possible reexposure to an STD as they have a high rate of reinfection within 6 months after treatment.
- Exclude BV
- Sex partners to be evaluated and treated
- Repeat alternative course of therapy
- Reevaluate to determine whether cervicitis has resolved

Referral criteria:

- Gynecologic referral to rule out other causes in case of persistent, unresponsive or recurrent cervicitis.

***Situation 2: At Super Specialty Facility in Metro location where higher-end technology is available**

a) Clinical Diagnosis:

Same as above

b) Investigations:

Same as above

In addition

- Colposcopy
- Cervical biopsy
- Microbial etiology of cervicitis to be delineated (indicated in patients with recurrent or persistent cervicitis) as per relevance in a given clinical situation, any of the following tests may be done.
 - isolation of *C. Trachomatis*
 - culture for *N. Gonorrhoeae*
 - HSV culture: viral isolation
 - Isolation of *T. Vaginalis*
 - immunologic detection of microbial antigens
 - use of nucleic acid probes
 - DNA amplification / detection methods.
- NAAT should be used for diagnosing *C. trachomatis* and *N. gonorrhoeae* in women with cervicitis

Treatment:

- For reasons that are unclear, cervicitis can persist despite repeated courses of antimicrobial therapy.
- Most persistent cases not caused by relapse or reinfection with *C. trachomatis* or *N. gonorrhoeae*
- Other factors like persistent abnormality of vaginal flora, douching, exposure to other types of chemical irritants or idiopathic inflammation in the zone of ectopy to be evaluated

VI. FURTHER READING / REFERENCES

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NAME OF CONDITION: Epididymitis

I. WHEN TO SUSPECT/ RECOGNIZE?

Case definition:

Epididymitis is inflammation of epididymis resulting in pain, swelling and tenderness of the scrotal sac. Many cases are related to genitourinary tract infections, especially sexually transmitted infections and bacterial urinary tract infections. The process causes scrotal pain and swelling that is characteristically unilateral and relatively acute in onset. It can be of two types

1. **Acute epididymitis:** pain, swelling, and inflammation of the epididymis lasting <6 weeks. In most cases of acute epididymitis, the testis is also involved in the process (**epididymo-orchitis**).
2. **Chronic epididymitis** is characterized by a ≥ 6 week history of discomfort, pain or swelling in the epididymis. Generally seen in conditions with granulomatous reaction e.g tuberculosis (most common granulomatous disease affecting the epididymis). Tuberculous epididymitis should be suspected in all patients whose clinical status worsens despite appropriate antibiotic treatment.

Causes of acute epididymitis

1. Among sexually active men (<35 years)

- Most frequently- *C. trachomatis* or *N. gonorrhoeae*.
- Sexually transmitted enteric organisms e.g., *Escherichia coli* and *Pseudomonas* spp.

Sexually transmitted acute epididymitis usually is accompanied by urethritis, which frequently is asymptomatic.

2. In men aged >35 years

- Sexually transmitted epididymitis is uncommon
- Bacteriuria secondary to obstructive urinary disease (e.g., benign prostatic hyperplasia)
- Association with urinary tract instrumentation, surgery, systemic disease and immunosuppression.

Sequelae

- Abscess formation

- Infarction of the testicle
- Gangrene of the testicle
- Subfertility or Infertility
- Chronic epididymalgia or epididymitis

II. INCIDENCE OF THE CONDITION IN OUR COUNTRY

Epididymitis is common, and it carries much morbidity in terms of suffering and loss of time from work. Researchers have reported that the incidence of epididymitis may range from one to four per 1000 men per year^{3,4}. No institutional data available in India.

III. DIFFERENTIAL DIAGNOSIS (non RTIs/STIs)

- Testicular torsion: surgical emergency, occurs more frequently in adolescents and in men without evidence of inflammation or infection.
- Infections: Filariasis, Coliforms or pseudomonas infection, Mumps virus infection, fungal infection
- Non infectious causes: Trauma, Hernia, Hydrocoele, Testicular tumor, testicular infarction

IV. PREVENTION AND COUNSELING

General measures as applicable to all patients with suspected STIs

- Educate and counsel patient and sex partner(s) regarding RTIs/STIs, genital cancers, safer sex practices and importance of taking complete treatment.
- Treat partner(s) for the suspected organisms.
- Advise sexual abstinence during the course of treatment to minimize transmission.
- Promote the use of barrier contraception like condoms, educate about correct and consistent use.
- Refer for voluntary counseling and testing for HIV, Syphilis and Hepatitis B.
- Consider immunization against Hepatitis B.

- Schedule return visit after 7 days to ensure treatment compliance as well as to see reports of tests done.
- If symptoms persist, assess whether it is due to treatment failure or reinfection and advise prompt referral.

V. OPTIMAL DIAGNOSTIC CRITERIA, INVESTIGATIONS, TREATMENT & REFERRAL CRITERIA

*Situation 1: At Secondary Hospital/ Non-Metro situation: Optimal Standards of Treatment in Situations where technology and resources are limited

Clinical Diagnosis:

In a male suffering from urethritis, the onset of scrotal tenderness and swelling suggests the diagnosis of epididymitis.

Clinical diagnosis is based on

- Examination
 - erythema or asymmetry in scrotal size
 - scrotal swelling, minimal or more apparent
 - penile size, oedema or phimosis should be examined
 - Meatal erthema, discharge (thick, creamy or mucopurulent).
 - Milking the penis (urethra) may produce discharge at the meatus.
 - Shaft of penis with papules, nodules, ulcers or other skin lesions.
- Palpation
 - Of inguinal region for tender lymphnodes.
 - Of spermatic cords to rule out tenderness, asymmetry, and thickening
 - Of scrotum to assess for asymmetry, tenderness and consistency of testes and epididymis.
- Transillumination: to rule out hydrocoele.
- Hernia to be assessed for.

Clinical features

- Unilateral testicular pain and tenderness
- Hydrocele and palpable swelling of the epididymis
- Inflammation and swelling usually begins in the tail of the epididymis and spreads to involve the rest of the epididymis and testicle.
- Spermatic cord tender and swollen.

Investigations:

To assess for

- a) urethritis and urinary-tract infection
- b) to rule out the various differentials

These include

- Gram stain of urethral secretions demonstrating ≥ 5 WBC per oil immersion field. If normal, then epididymitis as a cause of scrotal pain is highly unlikely.
- Positive leukocyte esterase test on first-void urine
- Microscopic examination of first-void urine sediment demonstrating ≥ 10 WBC per high power field.
- Urine culture: In asymptomatic patients colony counts of $>1 \times 10^5$ cfu/ml of urine is significant. In cases with acute dysuria and frequency colony count of 1×10^2 cfu/ml bacteria is the most useful criterion. Also aids in identification of gram species.
- Testing for other STDs as the setting suggests.
- Ultrasound: Primarily used for ruling out torsion of the spermatic cord. Otherwise, minimal utility in a clinical presentation consistent with epididymitis. Reserved for patients with scrotal pain who cannot be diagnosed accurately by physical examination, history, and objective laboratory findings.

Treatment:

Standard Operating procedure

- **Empiric therapy is indicated before laboratory test results are available.**

- Treat for *C. trachomatis* and *N. gonorrhoeae*
- Goals of treatment are
 - microbiologic cure of infection,
 - improvement of signs and symptoms,
 - prevention of transmission to others
 - decrease in potential complications (e.g., infertility or chronic pain).

Adjunct therapy

- Bed rest with scrotal elevation with T bandage
- Analgesics are recommended until fever and local inflammation have subsided.
- Treat for both gonococcal and chlamydial infections.

Recommended regime

- Tab Cefixime 400 mg orally BD for 7 days
- OR**
- Inj. Ceftriaxone 250 mg IM in a single dose
- PLUS**
- Cap. Doxycycline 100mg orally, twice daily for 14 days
- **Additional therapy** to include a fluoroquinolone
 - if infection not found to be caused by gonorrhoea or
 - if enteric organisms are more likely (e.g., MSM who report insertive anal intercourse).
 - Or if significant gram negative bacteriuria is present.

In these cases

- T. Levofloxacin 500 mg orally once daily for 10 days
- OR**
- T. Ofloxacin 300 mg orally twice a day for 10 days
- If gonococcal infection is confirmed (or is highly likely), patient to be hospitalised and parenteral cephalosporin (Ceftriaxone) to be started as it is a complicated gonococcal infection. A longer duration of treatment may be needed. (Refer to guidelines on urethral discharge)

Syndrome specific guidelines for partner management

- Patients to be instructed to refer sex partners for evaluation and treatment if their contact with the index patient was within the 60 days preceding onset of their own symptoms.
- Instructed to abstain from sexual intercourse until they and their sex partners have been adequately treated (i.e., until therapy is completed and patient and partners no longer have symptoms).
- Partner needs to be treated depending on the clinical findings

Management protocol in case the partner is pregnant

- Depending on the clinical findings in the pregnant partner (whether vaginal discharge or endocervical discharge or PID is present) the drug regimens should be used.
- Doxycycline is contraindicated in pregnancy
- Erythromycin base/Amoxicillin can be used in pregnancy (Erythromycin estolate is contraindicated in pregnancy due to hepatotoxicity), Erythromycin base or erythromycin ethyl succinate should be given)

In patient care

Hospitalization to be considered

- When severe pain suggests other diagnoses (e.g., torsion, testicular infarction, or abscess)
- When patients are unable or unlikely to comply with an antimicrobial regimen
- High fever is uncommon in epididymitis and indicates a complicated infection; these patients should be admitted for further evaluation
- Parenteral therapy to be started in view of complicated gonococcal infection.

Follow-Up

- Instructed to return if symptoms fail to improve within 48 hours of the initiation of treatment. Requires re-evaluation of the diagnosis and therapy.
- After completion of antibiotic therapy: Swelling and tenderness that persist after completion should be evaluated comprehensively to assess for tumor, abscess, infarction, testicular cancer, TB, and fungal epididymitis.

Special Considerations

HIV Infection

- Same treatment regimen as those who are HIV negative.
- Other etiologic agents implicated in acute epididymitis with HIV infection include CMV, salmonella, toxoplasmosis, *Ureaplasma urealyticum*, *Corynebacterium* sp., *Mycoplasma* sp., and *Mima polymorpha*.
- Fungi and mycobacteria are also more likely to cause acute epididymitis in this setting.

Referral criteria:

- If the diagnosis is questionable, then immediate referral to urologist to preserve testicular viability.

***Situation 2: At Super Specialty Facility in Metro location where higher-end technology is available**

c) Clinical Diagnosis:

Same as above

d) Investigations:

Same as above

PLUS

- Culture for gonococcus
- Nucleic acid hybridization tests and NAATs: aid in quick detection of both *N. gonorrhoeae* and *C. trachomatis*. Done on urethral swab specimens (NAAT can be performed on urine as well). Because of their higher sensitivity, amplification tests are preferred for the detection of *C. trachomatis*.
- Radionuclide scanning of the scrotum (most accurate radiologic method of diagnosis, but it is not routinely available).

e) Treatment:

Same as above

f) Referral criteria:

Same as above

AND

Surgical management (if required)

- Surgical drainage of testicular abscesses, Orchiectomy, Epididymectomy might be indicated in an older group of patients BUT ONLY after unsuccessful conservative treatment.
- Surgical therapy (generally orchiectomy) may be necessary for complications of severe epididymoorchitis, such as testicular infarction, abscess formation, development of a pyocele of the scrotum (infected hydrocele).

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NAME OF CONDITION: GENITAL (INCLUDING ANAL/ PERIANAL) ULCER DISEASE [GUD]

I. WHEN TO SUSPECT/ RECOGNIZE?

a. Case definition:

Any ulcer present in the genital, anal or perianal area needs to be reviewed to rule out the possibility of sexually transmitted infections, although non-sexually transmitted causes may also be responsible.

b. Introduction:

The causes of sexually transmitted ulcers are:

- Genital herpes
- Syphilis
- Chancroid
- Lymphogranuloma Venereum
- Donovanosis

GUD especially with HSV, syphilis, and chancroid have been associated with an increased risk for HIV transmission,

II. INCIDENCE OF THE CONDITION IN OUR COUNTRY:

Institutional data on prevalence and incidence not available. The frequency of each cause differs by geographic area and population. Genital herpes is the most prevalent of these. More than one etiologic agent can be present in an ulcer. The clinical diagnosis of GUD is undermined when HIV infection is present. Diagnosis based on clinical impression may not always be correct. The etiology of GUD according to M-PCR was reported to be HSV in 26%, chancroid in 23%, primary syphilis in 10%, and multiple infections in 7% cases¹. Also, HIV seroprevalence is significantly higher in patients with HSV compared with other etiologies presumably because of HIV-induced immunosuppression and consequent HSV reactivation. All this calls for syndromic management of genital ulcers especially in the setting of HIV.

III. DIFFERENTIAL DIAGNOSIS

Non sexually transmitted genital ulcers include:

- Yeast
- Trauma
- Carcinoma
- Aphthae and Behcet's
- Fixed drug eruption
- Psoriasis

IV. PREVENTION AND COUNSELING

General measures as applicable to all patients with suspected STIs

- Educate and counsel patient and sex partner(s) regarding RTIs/STIs, genital cancers, safer sex practices and importance of taking complete treatment.
- Treat partner(s) for the suspected organisms.
- Advise sexual abstinence during the course of treatment to minimize transmission.
- Promote the use of barrier contraception like condoms, educate about correct and consistent use.
- Refer for voluntary counseling and testing for HIV, Syphilis and Hepatitis B.
- Consider immunization against Hepatitis B.
- Schedule return visit after 7 days to ensure treatment compliance as well as to see reports of tests done.
- If symptoms persist, assess whether it is due to treatment failure or reinfection and advise prompt referral.

V. OPTIMAL DIAGNOSTIC CRITERIA, INVESTIGATIONS, TREATMENT & REFERRAL CRITERIA

***Situation 1: At Secondary Hospital/ Non-Metro situation: Optimal Standards of Treatment in Situations where technology and resources are limited**

a) **Clinical Diagnosis:**

- Clinical examination of the genital area to confirm the presence of ulcers.
- Ulcers to be examined for location, number (single, multiple), superficial (erosions) or deep, edge (undermined/punched out), margins regular/irregular) and floor (presence of exudates, slough/granulation tissue). Palpation of ulcers for tenderness, induration of the floor and edges or bleeding on maneuvering.
- Palpation of inguinal region for lymph nodes in terms of tenderness, increased warmth, superficial or deep, discrete or matted, free mobility or fixity to deeper structures, consistency (firm or soft) and fluctuance.

b) **Investigations:**

Standard tests for all patients with genital ulcer

- **Testing for HIV:** on all persons with genital, anal, or perianal ulcers who are not known to have HIV infection
- **Serologic** tests for syphilis
- **Smear** from the base of ulcer, **Gram** stained (for chancroid) and **Giemsa** stained (for herpes and donovanosis)
- **Biopsy** at times- for unusual causes or those that do not respond to initial therapy.
- **Type-specific serologic tests for HSV:** useful to identify pregnant women at risk for HSV infection and to guide counseling regarding the risk for acquiring genital herpes during pregnancy. To be offered to uninfected women whose sex partner has HSV infection.

c) **Treatment:**

- Treat patients before test results are available
- Empirically treat for the diagnosis considered most likely on the basis of clinical presentation and epidemiologic circumstances (including travel history) as even after extensive investigations, at least 25% of patients will have no laboratory-confirmed diagnosis.

Standard Operating procedure

On the basis of clinical examination and investigations, decide whether the ulcers are **herpetic** or **non-herpetic**

- **If vesicles or multiple painful ulcers are present**

Treat for herpes

- Tab. Acyclovir 400mg orally, three times a day for 7-10 d
OR
- Tab Acyclovir 200mg five times a day for 7-10 d
OR
- Tab Famciclovir 250mg three times a day for 7-10 d
OR
- Tab Valacyclovir 1 g twice a day for 7-10 d
 - Initiation of therapy within 1 day of lesion onset or during the prodrome
 - Patient to be provided with a supply of drug or a prescription with instructions to initiate treatment immediately when symptoms begin.
 - Suppressive therapy in select cases
- **If vesicles are not seen and only ulcer is seen**

Treat for **syphilis** and **chancroid** and counsel on herpes genitalis

To cover syphilis

- Inj Benzathine penicillin 2.4 million IU IM after test dose in two divided doses (with emergency tray ready)
- In individuals allergic or intolerant to penicillin Tab Doxycycline 100mg orally, twice daily for 14 days

Plus

To cover chancroid

- Tab Azithromycin 1g orally single dose
OR
- Inj. Ceftriaxone 250 mg IM single dose
OR

- Tab. Ciprofloxacin 500mg orally, twice a day for three days

Treatment should be extended beyond 7 days if ulcers have not reepithelialised

Suppressive Therapy for Recurrent Genital Herpes

- Reduces the frequency of genital herpes recurrence by 70%–80%, improves quality of life.
- Also effective in patients with less frequent recurrences.
- Safety and efficacy documented with acyclovir for as long as 6 years and with valacyclovir or famciclovir for 1 year.
- The frequency of recurrent outbreaks diminishes with time. Also, the patient’s psychological adjustment to the disease might change. Therefore, during suppressive treatment (e.g., once a year), re-discuss the need to continue therapy.
- Acyclovir treatment late in pregnancy reduces the frequency of cesarean sections among women who have recurrent genital herpes by diminishing the frequency of recurrences at term.
- Drugs recommended: for as long as required
 - **Tab Acyclovir** 400mg BD
 - **Famciclovir** 250 mg orally twice a day
 - **Valacyclovir** 500 mg orally once a day
 - **Valacyclovir** 1g orally once a day

Counselling of persons with genital HSV infection:

- Educate concerning the natural history, potential for recurrent episodes, asymptomatic viral shedding, and risk of sexual transmission.
- Advise that suppressive therapy is available for preventing symptomatic recurrent episodes
- Episodic therapy to shorten the duration of episodes.
- Encourage to inform current and future partners.

- Remain abstinent from sexual activity with uninfected partners when lesions or prodromal symptoms are present.
- Male latex condoms, used consistently and correctly, might reduce the risk of transmission
- Sex partners to be advised that they might be infected even if they have no symptoms. Type-specific serologic testing of the asymptomatic partners recommended to determine whether they are already HSV seropositive or are at risk for acquiring HSV.
- The risk for neonatal HSV infection should be explained to all persons, males and females. Increased risk if infection acquired for the first time near delivery.
- Pregnant women and women of childbearing age **with genital herpes** encouraged to inform their health care providers during pregnancy and those who will care for their newborn infant about their infection (**risk of neonatal herpes is high**).
- Pregnant women who are **not known to be infected** with HSV-2 should be advised to abstain from intercourse with men who have genital herpes during the third trimester of pregnancy.
- **Asymptomatic persons diagnosed with serologic evidence of HSV-2** should receive the same counseling messages as persons with symptomatic infection.

Syndrome specific guidelines for partner management

- Treat all partners who are in contact with client in last 3 months
- Partners should be treated for syphilis and chancroid
- Advise sexual abstinence during the course of treatment
- Provide condoms, educate about correct and consistent use
- Refer for voluntary counseling and testing for HIV, Syphilis and Hepatitis B
- Schedule return visit after 7 days

Management of HIV infected patients

- To be monitored closely. More likely to experience treatment failure and heal slowly
- Might require repeated or longer courses of therapy

- Treatment failures can occur with any regimen.
- Ceftriaxone and Azithromycin based regimens used only if follow-up can be ensured.

Management of Pregnant Women

- Quinolones (like ofloxacin, ciprofloxacin), doxycycline, sulfonamides are **contraindicated** in pregnant women.
- **Pregnant women with positive RPR-** consider infected unless adequate treatment is documented in records and sequential serologic antibody titres have declined.
- **Pregnant women with primary, secondary, or latent syphilis:** Two doses of Inj Benzathine penicillin 2.4 million IU IM after test dose (with emergency tray ready) at 1 week interval.
- **Pregnant women who are allergic to penicillin:**
 - Tab. Erythromycin 500mg orally four times a day for 15 days (Erythromycin estolate contraindicated in pregnancy)
 - Neonate to be treated for syphilis after delivery.
- All pregnant women should be asked history of **genital herpes** and examined carefully for herpetic lesions.
 - Women **without symptoms or signs of genital herpes** or its prodrome can deliver vaginally.
 - Women **with genital herpetic lesions at the onset of labour-** delivered by caesarean section to prevent neonatal herpes.
 - **Acyclovir** may be administered orally to pregnant women with first episode genital herpes or severe recurrent herpes. Considered a safe drug

Neonatal Herpes

- Infants exposed to HSV during birth should be followed carefully in consultation with a pediatric infectious disease specialist.
- Intravenous acyclovir considered for infants born to women who acquired HSV near term (as the risk for neonatal herpes is high for these infants).
- Intravenous acyclovir promptly started for infants who have neonatal herpes.

- The recommended regimen for infants treated for **known** or **suspected neonatal herpes** is acyclovir 20 mg/kg IV every 8 hours for 21 days for disseminated and CNS disease or for 14 days for disease limited to the skin and mucous membranes.

d) **Referral criteria:**

Refer to higher centre

- Cases of genital ulcer not responding to the above treatment protocols.
- Neonatal herpes if adequate monitoring and expertise not available

***Situation 2: At Super Specialty Facility in Metro location where higher-end technology is available**

g) **Clinical Diagnosis:**

Same as above.

h) **Investigations:**

Same as above

In addition

Specific tests for evaluation of genital, anal, or perianal ulcers which may be available in this situation and which may be required for specific diagnosis in difficult cases

- 1) Darkfield microscopy (from ulcer fluid or lymph node aspirate) to look for motile treponemes. If available, should be done for all suspected patients with syphilis.
- 2) Culture for *Haemophilus ducreyi*: not widely available; even when used, sensitivity is <80%
- 3) Multiplex PCR: to detect various possible causes in a genital ulcer
- 4) Surveillance cultures of mucosal surfaces (for HSV) might be considered for neonates possibly exposed to maternal herpes.
- 5) Donovanosis: visualization of dark-staining Donovan bodies on tissue crush preparation or biopsy.

i) Treatment:

Same as above

In Addition

Severe HSV disease

- Intravenous (IV) acyclovir therapy: for patients with severe HSV disease or complications that necessitate hospitalization (e.g., disseminated infection, pneumonitis, or hepatitis) or CNS complications (e.g., meningoencephalitis).
- Recommended regime
 - Inj Acyclovir 20 mg/kg IV every 8 hours for 2–7 days or until clinical improvement is observed, followed by oral antiviral therapy to complete at least 10 days of total therapy.
- Dose adjustment for impaired renal function.

j) Referral criteria:

Non- Responsive ulcers (to recommended treatment protocol)

Causes of no improvement after 7 days follow up

- incorrect diagnosis
- coinfection with another STD
- HIV infection
- Non-compliance
- Resistance to antimicrobial used

Other factors to be accounted for

- Large size of ulcer
- Slower healing in uncircumcised men
- Presence of fluctuant lymphadenopathy- may need drainage
- Donovanosis: typically slow healing. Recommended treatment is Tab Doxycycline 100 mg bd for at least three weeks or till lesions is healed.

VI. FURTHER READING / REFERENCES

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NAME OF CONDITION: GENITAL WARTS

I. WHEN TO SUSPECT/ RECOGNIZE?

Introduction:

Genital warts are single or multiple soft, painless, flat, papular, or pedunculated growths which appear around the anus, vulvovaginal area, penis, urethra and perineum. May also appear as keratinized papules. Common sites are

- Women: around the introitus
- Men: under the foreskin, on the shaft
- Both: On the anogenital epithelium, within the anogenital tract.

Causative organism:

- Caused by Human Papilloma virus (HPV) Type 6 or 11 (90% cases)
- HPV types 16, 18, 31, 33, and 35 found occasionally and associated with high-grade intraepithelial neoplasia.

Symptoms:

- Usually asymptomatic
- Depending on the size and anatomic location, can be painful or pruritic.

II. INCIDENCE OF THE CONDITION IN OUR COUNTRY

Epidemiological studies show genital warts to be the most common sexually transmitted diseases. The population-based incidence of genital warts is estimated to be 106-160 cases per 100,000 population in the west, with the highest incidence rates in young adults aged 15-25 years. Genital warts affect approximately 30 million individuals worldwide. The case load in India is estimated to be above 3 million (only extrapolated data, no well defined population based statistics available).

III. DIFFERENTIAL DIAGNOSIS

- Condyloma lata (syphilis)
- Molluscum contagiosum
- Bowenoid papulosis
- Lichen planus and nitidus
- Pearly penile papules

- Seborrheic keratoses
- Fordyce's spots

IV. PREVENTION AND COUNSELING

General measures as applicable to all patients with suspected STIs

- Educate and counsel patient and sex partner(s) regarding RTIs/STIs, genital cancers, safer sex practices and importance of taking complete treatment.
- Treat partner(s) for the suspected organisms.
- Advise sexual abstinence during the course of treatment to minimize transmission.
- Promote the use of barrier contraception like condoms, educate about correct and consistent use.
- Refer for voluntary counseling and testing for HIV, Syphilis and Hepatitis B.
- Consider immunization against Hepatitis B.
- Schedule return visit after 7 days to ensure treatment compliance as well as to see reports of tests done.
- If symptoms persist, assess whether it is due to treatment failure or reinfection and advise prompt referral.

Key counseling messages to be conveyed to all patients diagnosed with HPV infection:

- Genital HPV infection is very common and can also be spread by oral- sexual contact.
- It usually has no signs or symptoms.
- Mostly, clears spontaneously. Some infections do progress to genital precancers, and cancers.
- The types of HPV causing genital warts are different from the ones causing anogenital cancers.
- Treatments are available for the conditions caused by HPV but not for the virus itself.
- Warts do not affect a woman's fertility or ability to carry a pregnancy to term.
- Correct and consistent male condom use lowers the chances of giving or getting genital HPV does not protect fully.
- To lower the chances of getting infection, limit the number of partners.

HPV vaccines

Two types which offer protection against the HPV types 16 and 18 that cause 70% of cervical cancers.

- Cervarix: bivalent vaccine against Type 16 and 18 (0.5 ml IM at 0,1 and 6 mths)
- Gardasil: quadrivalent vaccine which also protects against the types 6 and 11. Three doses (0.5 ml IM at 0,2 and 6 months)

Most effective when all three doses have been administered before any sexual contact.

V. OPTIMAL DIAGNOSTIC CRITERIA, INVESTIGATIONS, TREATMENT & REFERRAL CRITERIA

*Situation 1: At Secondary Hospital/ Non-Metro situation: Optimal Standards of Treatment in Situations where technology and resources are limited

Clinical Diagnosis:

- Presumptive Diagnosis based on clinical examination (inspection)
- History of exposure followed by signs and symptoms is contributory towards diagnosis.

On examination, genital warts can be

- Single or multiple
- Soft or verrucous
- Asymptomatic, may be painful occasionally

Investigations:

- Aceto-white test: Application of 3%–5% acetic acid, which causes HPV-infected genital mucosa to turn white in color.
- Biopsy: might be indicated if
 - the diagnosis is uncertain
 - the lesions do not respond to standard therapy
 - the disease worsens during therapy
 - the lesion is atypical
 - the patient has compromised immunity

- the warts are pigmented, indurated, fixed, bleeding, or ulcerated.
- The lesion shows a high risk of atypia
- HPV DNA testing: Not recommended on a routine basis as test results would not alter clinical management of the condition.

Treatment:

- Should be guided by the preference of the patient, available resources, and the experience of the health-care provider.
- No definitive evidence that any of the available treatments are superior to any other
- No single treatment is ideal for all patients or all warts.
- Spontaneous resolution of lesions may also occur.

Recommended regimens: (NACO recommended)

I. Penile and Perianal warts (external warts)

20% Podophyllin in compound tincture of benzoin

II. Cervical warts

- Podophyllin is contraindicated.
- Biopsy of warts to rule out malignant change.
- Cryo cauterization is the treatment of choice.
- Cervical cytology should be periodically done in the sexual partner(s) of men with genital warts.
- The treatment modality should be changed if a patient has not improved substantially after a complete course of treatment or if side effects are severe.

Alternate Regimens for External Genital Warts

Self applied

- Imiquimod 5% cream

Provider administered

- Cryotherapy: repeat application every 1-2 weeks
- Trichloroacetic acid: weekly applications
- Surgical removal: scissor excision, curettage, electrosurgery, radiosurgery

Alternate Regimens for Cervical Warts

- Management of exophytic cervical warts should include consultation with a specialist

Special situations

1. Vaginal Warts

- Cryo-cuaterisation
- TCA or BCA 80%–90% applied to warts.

2. Urethral Meatus Warts

- Cryotherapy with liquid nitrogen
- Podophyllin 10%–25% in compound tincture of benzoin.
- Imiquimod use

3. Anal Warts

- Cryotherapy with liquid nitrogen
- TCA or BCA 80%–90% applied to warts.
- Surgical removal
- Intra-anal warts should be managed in consultation with a surgical specialist for digital examination, standard anoscopy, or high-resolution anoscopy.

Alternative Regimens

- intralesional interferon
- photodynamic therapy
- topical cidofovir.

Special Considerations

Pregnancy

- Imiquimod, podophyllin not to be used
- genital warts can proliferate and become friable
- Removal of warts during pregnancy can be considered, though resolution might be incomplete or poor until pregnancy is complete.
- Cesarean delivery for women with genital warts is indicated if
 - pelvic outlet is obstructed

- Vaginal delivery would result in excessive bleeding.
- HPV types 6 and 11 can rarely cause respiratory papillomatosis in infants and children. Whether cesarean section can prevent this is unclear, hence this is not an absolute indication for caesarean delivery

HIV Infection

- more likely to develop genital warts
- Lesions are more recalcitrant to treatment
- Same treatment regimes to be followed, however, might not respond as well and might have more frequent recurrences after treatment
- Squamous cell carcinomas arising in or resembling genital warts are more frequent, hence biopsy for confirmation of diagnosis in suspicious cases.
- Screening for anal intraepithelial neoplasia by cytology recommended in HIV-infected MSM.

Squamous Cell Carcinoma in Situ

- referred to a specialist for treatment
- Ablative modalities usually are effective
- Careful follow-up is essential

Referral to specialists:

Cervical Intraepithelial neoplasia

Invasive cervical squamous cell carcinoma

Penile Intraepithelial Neoplasia

Anal intraepithelial neoplasia or carcinoma

***Situation 2: At Super Specialty Facility in Metro location where higher-end technology is available**

k) Clinical Diagnosis:

Same as above

l) Investigations:

Same as above

m) Treatment:

Same as above

VI. FURTHER READING / REFERENCES

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4. Weiner RL, Koutsky LA. Genital Human papilloma virus infection. In *Sexually Transmitted Diseases* Eds: Holmes KK, Sparling PF, Stamm WE, Piot P, Wasserheit JN, Corey L, Cohen MS, Watts DH, Nelson RA. 4th Edition, 2008 McGraw-Hill, p490-508.

NAME OF CONDITION: Pelvic Inflammatory disease (PID)

I. WHEN TO SUSPECT/ RECOGNIZE?

a) Case definition:

Pelvic inflammatory disease (PID) comprises a spectrum of upper genital tract inflammatory disorders among women, which includes any combination of endometritis, salpingitis, tuboovarian abscess, and pelvic peritonitis¹.

1. Includes infections of the upper genital tract by microorganisms ascending from the cervix or vagina
2. Excludes blood-borne infections such as tuberculosis.
3. Also infections following delivery or induced abortion are also categorized separately as puerperal or postabortion infection.

b) Introduction:

Various causative organisms include

1. Sexually transmitted organisms, especially *N. gonorrhoeae* and *C. trachomatis*,
2. Microorganisms that comprise the vaginal flora (e.g., anaerobes, *G. vaginalis*, *Haemophilus influenzae*, enteric Gram-negative rods, and *Streptococcus agalactiae*)².
3. Others like: Cytomegalovirus (CMV), *M. hominis*, *U. urealyticum*, and *M. genitalium* associated in some cases.

Often more than one species from vaginal flora isolated (“polymicrobial” PID). No microorganisms are recovered from 20-30% of patients. A large number of unculturable species which are normal residents of the genital tract may have role to play.

Clinical features:

The presentation may be **Acute** or **Chronic**.

Important clinical signs and symptoms include

- Vaginal/cervical discharge, congestion or ulcers
- Menstrual irregularities like heavy irregular vaginal bleeding, dysmenorrhoea,

- Dyspareunia, Dysuria or tenesmus
- Temperature > 39 degree C
- Lower abdominal tenderness or guarding
- Uterine/adnexal tenderness, cervical movement tenderness,
- Presence of a pelvic mass

PID can present with a vast array of clinical manifestations

- **Salpingitis** is the most important feature of PID.
- Infection and inflammation of the endometrium, blood vessels and lymphatics without visually recognized salpingitis.
- None of the symptoms, clinical signs, or laboratory results are pathognomonic for PID. About two-thirds of cases of PID are probably unrecognized.⁴
- **Chronic PID** is an even more poorly defined entity used for patients with chronic pain or infertility, caused by pelvic adhesions and other abnormalities from a prior episode

Sequelae

Sequelae are common.

- Tubal infertility due to tubal and peritubal damage
- Ectopic Pregnancy
- Chronic pain and other gynecological morbidity

II. INCIDENCE OF THE CONDITION IN OUR COUNTRY

The exact incidence of PID is unknown, because the disease cannot be diagnosed reliably from clinical symptoms and signs. Direct visualization of the fallopian tubes by laparoscopy is the **best single diagnostic test**, but it is invasive, lacks sensitivity, and is not used routinely in clinical practice.

PID is the most common gynaecological reason for admission to hospital in the USA. In resource-poor countries it accounts for 17% to 40% of gynaecological admissions in sub-Saharan Africa, 15% to 37% in Southeast Asia, and 3% to 10% in India (3).

III. DIFFERENTIAL DIAGNOSIS

- In **mild cases**
 - Rule out various causes of vaginal discharge.
- In **severe cases**
 - Rule out causes of acute abdomen, including ectopic pregnancy and acute appendicitis.
 - Other gynecological differentials include rupture, bleeding, or torsion of an ovarian cyst, pelvic endometriosis.
 - Mesenteric lymphadenitis, regional ileitis, enteritis, and other manifestations of inflammatory bowel disease.
 - Urinary tract infection and colic from renal or ureteral stones.

IV. PREVENTION AND COUNSELING

General measures as applicable to all patients with suspected STIs

- Educate and counsel patient and sex partner(s) regarding RTIs/STIs, genital cancers, safer sex practices and importance of taking complete treatment.
- Treat partner(s) for the suspected organisms.
- Advise sexual abstinence during the course of treatment to minimize transmission.
- Promote the use of barrier contraception like condoms, educate about correct and consistent use.
- Refer for voluntary counseling and testing for HIV, Syphilis and Hepatitis B.
- Consider immunization against Hepatitis B.
- Schedule return visit after 7 days to ensure treatment compliance as well as to see reports of tests done.
- If symptoms persist, assess whether it is due to treatment failure or reinfection and advise prompt referral.

V. OPTIMAL DIAGNOSTIC CRITERIA, INVESTIGATIONS, TREATMENT & REFERRAL CRITERIA

***Situation 1: At Secondary Hospital/ Non-Metro situation: Optimal Standards of Treatment in Situations where technology and resources are limited**

a) **Clinical Diagnosis:**

The clinical diagnosis of acute PID is imprecise.

- I. The PPV of a clinical diagnosis depends on the epidemiologic characteristics of the population. It is higher among sexually active young women (particularly adolescents), patients attending STD clinics, and those who live in other settings where the rates of gonorrhea or chlamydia are high.
- II. Many episodes of PID go unrecognized. Health-care providers should maintain a low threshold for the diagnosis of PID.

Clinical evaluation is aimed at

- A. RULING OUT THE NUMEROUS DIFFERENTIALS
- B. ASSESSING FOR SEVERITY OF DISEASE

A. RULING OUT THE NUMEROUS DIFFERENTIALS

A simple **stepwise algorithm** for a patient presenting with abdominal signs and symptoms and vaginal discharges suggestive of **Acute PID**

1. Pregnancy test:
 - If positive points towards Ectopic Pregnancy or other pregnancy complications.
 - If negative: then do wet mount or Gram stain of cervical/vaginal secretions.
2. In a Sexually active patient: presence of yellow cervical mucopus or the wet mount revealing WBC's outnumbering the number of epithelial cells makes **PID a probable diagnosis**
3. USG and explorative laparoscopy to exclude appendicitis or ruptured abscess.

No symptom or sign is pathognomonic of PID. All symptoms have a low positive and negative predictive value for the diagnosis of PID.

B. ASSESSING FOR SEVERITY OF DISEASE

1. SUBCLINICAL DISEASE (ATYPICAL PID, "SILENT" PID)
2. MILD AND MODERATELY SEVERE PID
3. SEVERE PID

Recommendations for diagnosing PID

Empiric treatment for PID should be initiated in sexually active young women and other women at risk for STDs,

- if there is pelvic or lower abdominal pain (with no other apparent cause)

AND

- if one or more of the following **minimum criteria** are present on pelvic examination:
 - a. cervical motion tenderness
OR
 - b. uterine tenderness
OR
 - c. adnexal tenderness.

Additional criteria to enhance the specificity of the minimum criteria and support a diagnosis

1. CLINICAL
 - oral temperature $>101^{\circ}\text{F}$ ($>38.3^{\circ}\text{C}$);
 - abnormal cervical or vaginal mucopurulent discharge (MPC)
 - cervical friability
2. LABORATORY
 - presence of abundant numbers of WBC on saline microscopy of vaginal fluid;
 - elevated erythrocyte sedimentation rate;
 - elevated C-reactive protein
 - laboratory documentation of cervical infection with *N. gonorrhoeae* or *C. trachomatis*.

Most specific criteria for diagnosing PID include: (NOT ROUTINELY RESORTED TO)

- endometrial biopsy with histopathologic evidence of endometritis
- transvaginal sonography or magnetic resonance imaging techniques showing thickened, fluid-filled tubes with or without free pelvic fluid or tubo-ovarian complex

- Doppler studies suggesting pelvic infection (e.g., tubal hyperemia)
- Laparoscopic abnormalities consistent with PID.

C. **Investigations:**

LABORATORY TESTS

- Vaginal smear demonstrating
 - increase in the inflammatory cells
 - presence of gonid (Gram's stain)
 - organism for BV or trichomoniasis
- Raised ESR (>15 mm/h)
- CRP: The mean CRP is 47 mg/L (range 32-63) for mild tubal abnormalities and 83 mg/L (range 65-103) for severe tubal disease.
- Peripheral WBC count (>10,000 mm³)
- Laparoscopy: Gives a more accurate diagnosis of salpingitis and more complete bacteriologic diagnosis. It has been the **gold standard** to diagnose PID. Criteria used to define salpingitis observed through the laparoscope include tubal erythema, swelling, and exudate. However, not practical and **not justified** for majority of cases when symptoms are mild or vague.
- Endometrial biopsy: for the outpatient diagnosis of subclinical or silent PID.
- Pregnancy test for all potentially fertile women with acute abdominal/pelvic pain irrespective of contraception use.
- Ultrasound examination: useful noninvasive test to diagnose and follow the course of severe PID.
- Transvaginal ultrasound
- Transvaginal power Doppler sonography
- Testing for *N. gonorrhoeae* and *C. trachomatis*: for a more specific diagnosis
- Microscopy and culture of urine
- Culdocentesis (USG guided): Its use has become less common to diagnose PID.

D. Treatment:

- Antimicrobial therapy is required to treat infection present in PID.
- Early antibiotic treatment in the first 3 days reduces tubal infertility.
- Choice of antimicrobial is empiric as collection and microbial testing of fallopian-tube specimens is not practical and reports take time in the majority of cases
- Antimicrobial regimen must cover at least the most frequently expected microbes i.e N. gonorrhoeae, C. trachomatis, and common aerobic and anaerobic isolates.
- At least two drugs are recommended for syndromic treatment of PID
- Treatment should be initiated as soon as the presumptive diagnosis has been made because prevention of long-term sequelae is dependent on early administration of appropriate antibiotics.

Treatment

Outpatient treatment

In mild or moderate PID

- Tab. Cefixime 400 mg orally BD for 7 days
PLUS
- Tab. Metronidazole 400mg orally, twice daily for 14 days
PLUS
- Tab Doxycycline, 100mg orally, twice a day for 2 weeks

Adjunctive treatment

- Tab. Ibuprofen 400mg orally, three times a day for 3-5 days
- Tab. Ranitidine 150mg orally, twice daily to prevent gastritis
- Remove intra uterine device, if present, under antibiotic cover of 24-48 hours
- Advise abstinence during the course of treatment and educate on correct and consistent use of condoms

Follow up

- Observe for 3 days, if no improvement i.e.
 - Fever persists

- No reduction in abdominal tenderness
- No reduction in cervical movement, adnexal and uterine tenderness
- If symptoms worsen

Refer for inpatient treatment

- Repeat testing of all women who have been diagnosed with chlamydia or gonorrhoea is recommended 3–6 months after treatment, regardless of whether their sex partners were treated

Syndrome specific guidelines for partner management

- Treat all partners in past 2 months
- Treat male partners for urethral discharge (Refer Guidelines)
- Advise sexual abstinence during the course of treatment
- Provide condoms, educate on correct and consistent use
- Refer for voluntary counseling and testing for HIV, Syphilis and Hepatitis B
- Inform about the complications if left untreated and sequelae
- Schedule return visit after 3 days, 7 days and 14 days to ensure compliance

Prevention

- Screening and treating sexually active women for chlamydia
- Whether the incidence of PID can be reduced by identifying and treating women with BV is unclear

Inpatient Treatment

Guidelines for the hospitalization of patients

- If no response; poor response to treatment; or worsening within 48-72 hrs
- Severe PID or signs of prostration, signs of peritonitis, septicaemia, nausea and vomiting, or high fever
- Surgical emergencies (e.g., appendicitis) cannot be excluded;
- Patient is pregnant;
- Patient unable to follow or tolerate an outpatient oral regimen

- Tubo-ovarian abscess.

Recommended Parenteral Treatment

Inj. **Cefotetan** 2 g IV every 12 hourly (better coverage against anaerobes)

OR

Inj. **Cefoxitin** 2 g IV every 6 hour (better coverage against anaerobes)

PLUS

Tab. **Doxycycline** 100 mg orally or IV every 12 hours (Preferably orally because of pain associated with intravenous infusion)

1. Clinical experience to guide decisions regarding transition to oral therapy
2. Usually can be shifted within 24–48 hours of clinical improvement
3. Oral therapy with doxycycline (100 mg twice a day) should continue to complete 14 days of therapy.

Alternative Regimes

1. Other second- or third-generation cephalosporins (e.g., ceftizoxime, cefotaxime, and ceftriaxone) **WITH** Doxycycline. Effective therapy for PID but are less active than cefotetan or cefoxitin against anaerobic bacteria.
2. Inj. Clindamycin 900 mg IV every 8 hours **WITH** Inj. Gentamicin loading dose IV or IM (2 mg/kg of body weight), followed by a maintenance dose (1.5 mg/kg) every 8 hours
Then Shift to Ongoing oral therapy with Tab. doxycycline 100 mg orally twice a day **OR** Tab Clindamycin 450 mg orally four times a day to complete a total of 14 days of therapy
3. Inj. Azithromycin for 1 week (500 mg IV for 1 or 2 doses followed by 250 mg orally for 5–6 days) **WITH** 12-day course of metronidazole.
4. Inj. Ceftriaxone 250 mg IM in a single dose **WITH** Tab. Doxycycline 100 mg orally twice a day for 14 days **WITH or WITHOUT** Metronidazole 500 mg orally twice a day for 14 day (better coverage against *N. gonorrhoeae*).

5. Inj. Cefoxitin 2 g IM in a single dose and Probenecid, 1 g orally administered concurrently in a single dose **WITH** Tab Doxycycline 100 mg orally twice a day for 14 days **WITH or WITHOUT** Tab Metronidazole 500 mg twice a day for 14 day
- If the culture for gonorrhea is positive, treatment should be based on results of antimicrobial susceptibility.

Special Considerations

Pregnancy

- High risk for maternal morbidity and preterm delivery
- Suspected PID should be hospitalized, treated with parenteral antibiotics.
- Doxycycline is contraindicated in pregnancy.
- Metronidazole is not recommended during the first three months. However, not to be withheld for a severely acute PID, which represents an emergency.

HIV Infection

- Standard parenteral and oral antibiotic regimens
- Microbes like *M. hominis*, candida, streptococcus apart from HPV infections and related cytologic abnormalities may be associated.

Intrauterine Contraceptive Devices

- Risk for PID confined to the first 3 weeks after insertion
- Insufficient evidence to recommend removal of IUDs in women with acute PID.
- Caution to be exercised if the IUD remains in place, close clinical follow-up is mandatory.

Referral criteria:

- The diagnosis is uncertain
- Surgical emergencies e.g. appendicitis or ectopic pregnancy cannot be excluded
- A pelvic abscess is suspected

***Situation 2: At Super Specialty Facility in Metro location where higher-end technology is available**

Clinical Diagnosis:

Same as above

Investigations:

Same as above

Plus

1. Cervical secretion or urine can be tested with NAAT (for *N. gonorrhoeae* or *C. trachomatis*): a positive test for either strongly increases the probability of PID.
2. Newer diagnostic techniques, such as PCR and antigen detection assays

Treatment:

Same as above

PLUS

For Tubo-Ovarian Abscess

- At least 24 hours of direct inpatient observation is recommended.
 - Initial parenteral therapy with Inj. Ampicillin/Sulbactam 3 g IV every 6 hour **WITH** Tab Doxycycline 100 mg orally or IV every 12 hour
- OR
- Ampicillin/sulbactam plus doxycycline is effective against *C. trachomatis*, *N. gonorrhoeae*, and anaerobes in women with tubo-ovarian abscess.
 - Clindamycin should be continued for oral therapy rather than doxycycline, because clindamycin provides more effective anaerobic coverage.

Standard Operating procedure

- a. In Patient
- b. Out Patient

c. Day Care

VI. FURTHER READING / REFERENCES

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NAME OF CONDITION: **Urethritis (Urethral discharge) in males**

I. WHEN TO SUSPECT/ RECOGNIZE?

a) Introduction:

Urethritis, manifested by urethral discharge, dysuria, or itching at the end of the urethra, is the response of the urethra to inflammation of any etiology. It is generally due to infection of the urethral mucosa with organisms (predominantly sexually transmitted, few cases non-sexually transmitted). **Symptoms**, if present, include discharge of mucopurulent or purulent material, dysuria, or urethral pruritus. **Asymptomatic** infections are also common.

b) Case definition:

The characteristic **physical finding** is urethral discharge, and the pathognomonic **confirmatory laboratory finding** is an increased number of polymorphonuclear leukocytes (PMNL) on Gram stain of a urethral smear or in the sediment of the first-voided urine.

c) Causative organisms: Urethritis can be

- **Gonococcal**, or gonorrhoea, when *Neisseria gonorrhoeae* is detected within the PMNL (may frequently be accompanied by chlamydial infections). Gonorrhoea is the second most commonly reported STI.
- **Nongonococcal** if *N. gonorrhoeae* cannot be detected in the PMNL. The term nongonococcal urethritis (NGU) has many causes and in most cases no pathogen can be detected. These include
 - *Chlamydia trachomatis*
 - *Mycoplasma genitalium*
 - *T. vaginalis*
 - HSV
 - Adenovirus
 - *Ureaplasma urealyticum*
 - Enteric bacteria

NGU occurring soon after curative therapy for urethral gonorrhoea is called Postgonococcal Urethritis (PGU).

II. INCIDENCE OF THE CONDITION IN OUR COUNTRY:

Among the cases of urethritis presenting to STD clinics, the incidence of gonococcal urethritis is close to 65% and that of Non gonococcal Urethritis (NGU) is 35%. The common organisms causing NGU were chlamydia (28%) ureaplasma (11%) and mycoplasma (11%)[Ref 1].

III. DIFFERENTIAL DIAGNOSIS:

Other causes of urethritis or urethral discharge which may not be sexually transmitted include

- Bacterial urethritis occurring in association with urinary tract infection, bacterial prostatitis, urethral stricture, phimosis, and secondary to catheterization or other instrumentation of the urethra.
- Urethritis with congenital abnormalities, chemical irritation, and tumors.
- Allergic etiology
- Stevens-Johnson syndrome may produce urethritis

Complications:

- NGU among males infected with *C. trachomatis* include epididymitis and Reiter's syndrome.
- GU- The following complications may arise

Complicated Gonococcal infection: Involves infection of urinary tract above the anterior urethra

- posterior urethrititis, periurethral abscess
- infection of Cowper's/ Tyson's glands
- urethral stricture
- prostatitis, epididymo-orchitis
- corneal perforation, blindness
- DGI (arthritis-dermatitis syndrome)

Disseminated Gonococcal Infection (DGI)

- Petechial or pustular acral skin lesions, asymmetrical arthralgia, tenosynovitis, or septic arthritis.
- b) Complicated occasionally by perihepatitis and rarely by endocarditis or meningitis.
- c) Some strains of *N. gonorrhoeae* that cause DGI can cause minimal genital inflammation.

IV. PREVENTION AND COUNSELING:

General measures as applicable to all patients with suspected STIs

- Educate and counsel patient and sex partner(s) regarding RTIs/STIs, genital cancers, safer sex practices and importance of taking complete treatment.
- Treat partner(s) for the suspected organisms.

- Advise sexual abstinence during the course of treatment to minimize transmission.
- Promote the use of barrier contraception like condoms, educate about correct and consistent use.
- Refer for voluntary counseling and testing for HIV, Syphilis and Hepatitis B.
- Consider immunization against Hepatitis B.
- Schedule return visit after 7 days to ensure treatment compliance as well as to see reports of tests done.
- If symptoms persist, assess whether it is due to treatment failure or reinfection and advise prompt referral.

V. OPTIMAL DIAGNOSTIC CRITERIA, INVESTIGATIONS, TREATMENT & REFERRAL CRITERIA

*Situation 1: At Secondary Hospital/ Non-Metro situation: Optimal Standards of Treatment in Situations where technology and resources are limited

Clinical Diagnosis:

Based on clinical examination of the amount, character and color of discharge.

- Urethral discharge should first be **objectively documented**.
- If not visible on initial examination, an attempt should be made to strip or milk the urethra from proximal to distal to elicit the discharge.
- If discharge still not detected, the patient should be examined the next morning, after not voiding overnight, to enhance the likelihood of reaching a firm diagnosis.

The **quantity** of discharge categorized as

- profuse (spontaneously flowing from the urethra),
- scant (apparent only after stripping the urethra),
- intermediate (between profuse and scant).

The **color or character** to be noted.

- A yellowish color (most common) or greenish color (seen only occasionally) can be described as “purulent.”
- A grey or white discharge often mixed with clear fluid should be labeled “mucoid” or “mixed.”
- The third category is “clear.”

The presence or absence of **meatitis**, penile edema and enlarged inguinal lymph node should be determined.

Investigations:

- I. To validate the inflammatory nature of urethral discharge and to differentiate between GU and NGU.
 - Gram stain of urethral secretions demonstrating ≥ 5 WBC per oil immersion field.
 - Positive leukocyte esterase test on first-void urine
 - Microscopic examination of first-void urine sediment demonstrating ≥ 10 WBC per high-power field.

Gram stain, preferred rapid diagnostic test for evaluating urethritis

- Highly sensitive and specific in males
 - Nongonococcal urethritis (NGU): microscopy indicates inflammation without GNID.
 - GU- High specificity (>99%) and sensitivity (>95%) for infection with *N. gonorrhoeae* in symptomatic men.
- II. For complicated GU or DGI
 - Haematological and Biochemical tests (to rule out systemic involvement)
 - Echocardiography

Treatment:

Standard Operating procedure

As dual infection is common and cannot be ruled out with reasonable certainty, the treatment for urethral discharge should adequately cover therapy for both, gonorrhoea and chlamydial infections (*Ref 5*).

- Treatment should be initiated as soon as possible after diagnosis.
- Single-dose regimens advantageous: improve compliance, can be directly observed.
- Treatment is mostly on an **outpatient** basis. Only cases with complicated gonococcal infections or disseminated gonococcal infections would require **inpatient** care.

A. Outpatient care

Recommended regimen for uncomplicated gonorrhoea + chlamydia

Uncomplicated infections (disease limited to the anogenital region (anterior urethra or rectum).

- Tab. Cefixime 400 mg orally, single dose
- Plus

- Tab Azithromycin 1 gram orally single dose under supervision
- Advise the patient to **follow up** after 7 days of start of therapy
- To minimize transmission, abstain from sexual intercourse for 7 days after single-dose therapy or until completion of a 7-day regimen
- To minimize reinfection, abstain from sexual intercourse until all sex partners are treated.
- All partners in the past 60 days before the initial diagnosis and any interim partners should be referred for evaluation and appropriate treatment.

Alternative drugs

- Ceftriaxone (single injection of 250 mg)
- Preferred in cases with oral sexual exposure (efficacy in treating pharyngeal infection)
- As of April 2007, quinolones no longer recommended for the treatment of gonorrhea and associated conditions, such as PID (*Ref 6*).

Follow up

After seven days

- To see reports of tests done for HIV, syphilis and Hepatitis B
- If symptoms persist, to assess whether it is due to treatment failure or reinfection
- For prompt referral if required
- Test of cure is not recommended unless therapeutic noncompliance or reinfection is suspected.

When symptoms persist or recur after adequate treatment for gonorrhea and chlamydia

or

If discharge or only dysuria persists after 7 days

- Reassess compliance and re-exposure: Retreatment with the initial regimen if not ensured
- Treatment completed but persistent symptoms and no objective signs of urethritis: only urinary alkalinisers, no extension of antimicrobial therapy.
- Persistent urethritis (objectively assessed): treat with T. doxycycline (100 mg bd for 7 days)
- Persistent urethritis (objectively assessed) after treatment with Doxycycline: might be caused by
 - doxycycline-resistant *U. urealyticum* or *M. genitalium*- treat with flouroquinolone (Ofloxacin) or macrolides (erythromycin).
 - *T. vaginalis*

- Prostatic infection
- Investigate these cases with culture or NAAT (PCR or TMA) on a urethral swab, first void urine or semen.
- Recommended regime while awaiting the results.

Recommended Regimens

- Metronidazole 2 g orally in a single dose

OR

- Tinidazole 2 g orally in a single dose

PLUS

- Azithromycin 1 g orally in a single dose (if not used for initial episode)
- Index patient and partner(s), should be treated for *Trichomonas vaginalis* with Tab. Secnidazole 2gm orally, single dose (to treat for *T. vaginalis*)

Persistence of chronic prostatitis/chronic pelvic pain syndrome

- Persistent pain (perineal, penile, or pelvic), discomfort, irritative voiding symptoms, pain during or after ejaculation, or new-onset premature ejaculation lasting for >3 months.
- A four-glass test to localize pathogens to the prostate.
- **Referral** to urologist should be considered. Providers should be alert to the possibility of in male patients experiencing

Alternative treatments for NGU

- Erythromycin base 500 mg orally four times a day for 7 days

OR

- Erythromycin ethylsuccinate 800 mg orally four times a day for 7 days

OR

- Levofloxacin 500 mg orally once daily for 7 days

OR

- Ofloxacin 300 mg orally twice a day for 7 days

Syndrome specific guidelines for partner management

- Partner management recommended for all males regardless of any specific etiology as substantial number of female partners are affected.
- All sex partners within the preceding 60 days should be referred for evaluation, testing, and empiric treatment
- Treat female partners on same lines after ruling out pregnancy and history of allergies

Management of pregnant partner

- Pregnant partners of male clients with urethral discharge should be examined by doing a per speculum as well as per vaginal examination
 - Should be treated for gonococcal as well as chlamydial infections (Refer guidelines for cervicitis).
 - Cephalosporins to cover gonococcal infection are safe and effective in pregnancy
 - Recommended treatment regime
 - o Tab. Cefixime 400mg orally, single dose
- OR
- o Ceftriaxone 125mg by intramuscular injection
- PLUS
- o Tab. Erythromycin 500mg orally four times a day for seven days
- OR
- o Cap Amoxicillin 500mg orally, three times a day for seven days to cover chlamydial infection

Special Considerations

HIV Infection

- Urethritis might facilitate HIV transmission.
- Same treatment regimen to be followed.

B. In Patient care

Required for

- few cases of complicated gonococcal urethritis needing intravenous cephalosporins
- disseminated gonococcal infection

Treatment

For complicated urethritis or Disseminated Gonococcal infection

- d) Hospitalization is recommended for initial therapy of DGI, especially for patients who might not comply, in whom diagnosis is uncertain, for those who have purulent synovial effusions or other complications.
- e) Examination for clinical evidence of endocarditis and meningitis should be performed.
- f) Persons treated for DGI should be treated presumptively for concurrent *C. trachomatis* infection.

Complicated / Disseminated infection

- Initial therapy: (Step1)
 - Ceftriaxone 1 g IM or IV 24 hourly
 - Cefotaxime 1 g IV 8 hourly
- Continue for seven days, may switch 24–48 hours after symptoms improve to (Step 2)
 - Cefixime 400 mg twice daily

Ophthalmia neonatorum

- Ceftriaxone 25–50 mg/kg (1gm) IV or IM as a single dose
- Cefotaxime 100 mg/kg IM as a single dose
- Frequent conjunctival irrigation with saline.

- Regimen to be continued for 24–48 hours after improvement begins
- Switched to cefixime 400 mg orally twice daily to complete at least 1 week of antimicrobial therapy.

Management of Sex Partners

- Partners are frequently asymptomatic
- All partners to be treated as per urethritis guidelines

Gonococcal Meningitis and Endocarditis

Recommended Regimen

Ceftriaxone 1–2 g IV every 12 hours

Referral to a higher centre required for cultures, inpatient treatment and monitoring

Referral criteria:

Refer to higher centre

- If the symptoms still persists after treatment step 1 and 2 and adequate partner treatment.

***Situation 2: At Super Specialty Facility in Metro location where higher-end technology is available**

Clinical Diagnosis

As in Situation 1

Investigations:

Steps as being followed in Situation 1 above

In addition

Other tests depending on availability: (not widely available)

- Culture for gonococcus and chlamydiae
- Nucleic acid hybridization tests and NAATs for detection of genitourinary infection with *N. gonorrhoeae*

Treatment:

Same as above for uncomplicated infection of urethra.

VI. WHO DOES WHAT? and TIMELINES

a. Doctors:

- **Dermatologist**

- History including detailed sexual history
- Examination
- Collection of specimen/s, preparation of smears
- Prescription of drugs according to requirement
- Follow up

- Counseling
- Determining the need for hospitalization
- Managing patients in intensive care units

- **Intensivist:**

- Monitoring patient with complications or disseminated disease.

- **Microbiologist:**

- Reporting of smears and cultures

b. Nurse:

- Assisting in examination
- Collection of blood samples
- Nursing care of patient in intensive care unit

c. Technician:

- Laboratory processing of specimens

- d. Counselor:
- Counseling the patient about safe sex practices
 - Voluntary testing of HIV
 - Promotion of barrier methods
 - Encouraging partner notification and adequate treatment

VII. FURTHER READING / REFERENCES

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5. Lyss SB, Kamb ML, Peterman TA, et al. *Chlamydia trachomatis* among patients infected with and treated for *Neisseria gonorrhoeae* in sexually transmitted disease clinics in the United States. *Ann Intern Med* 2003;139:178–85.
6. CDC. Update to CDC’s sexually transmitted diseases treatment guidelines, 2006: fluoroquinolones no longer recommended for treatment of gonococcal infections. *MMWR* 2007;56:332–6.

RESOURCES REQUIRED FOR ONE PATIENT / PROCEDURE (PATIENT WEIGHT 60 KGS)

(Units to be specified for human resources, investigations, drugs and consumables and equipment. Quantity to also be specified)

Situation	HUMAN RESOURCES	INVESTIGATIONS	DRUGS & CONSUMABLES	EQUIPMENT
1	1 Dermatologist 1 Microbiologist 1 Nurse 1 Technician 1 Counselor	Urethral smear for Gram's stain First voided urine for leukocyte esterase First voided urine for preparation of urinary sediment, staining and examination	Tab. Cefixime 400 mg orally, single dose Plus Tab Azithromycin 1 gram orally single dose under supervision	Slides Disposable urethral swabs Gloves Staining material Microscope
2	1 Dermatologist 1 Microbiologist 1 Intensivist 1 Nurse 1 Technician 1 Counselor	As for situation 1 plus Culture for gonococcus and chlamydiae (if available) Specific NAAT	As per situation 1 plus Injectable Ceftriaxone or Cefotaxime	As per situation 1 plus Paraphernalia for intensive care

NAME OF CONDITION: abnormal Vaginal discharge (abnormal)

I. WHEN TO SUSPECT/ RECOGNIZE?

a) Introduction:

Vaginal discharge is a fluid produced by glands in the vaginal wall and cervix that drains from the opening of the vagina. The amount and appearance of normal vaginal discharge varies throughout the menstrual cycle. An increased quantity of discharge from the vaginal orifice accompanied by discomfort, pain, itching or malodor for which the patient seeks treatment characterizes abnormal vaginal discharge. A large number of cases may also be asymptomatic or may have only minimal symptoms.

b) Causative organisms

The three diseases most frequently associated with vaginal discharge are

1. **Bacterial Vaginosis:** It is the most prevalent cause of vaginal discharge or malodor, however most women with BV were asymptomatic¹.
2. **Trichomoniasis:**
3. **Vulvo-vaginal candidiasis:**
 - a. **Uncomplicated VVC** which includes cases with sporadic or infrequent vulvovaginal candidiasis, mild-to-moderate symptoms, likely to be due to *C. albicans* or in non-immunocompromised women.
 - b. **Complicated VVC** which includes cases with recurrent vulvovaginal candidiasis, severe symptoms, non-albicans candidiasis or in women with uncontrolled diabetes, debilitation, or immunosuppression.

II. INCIDENCE OF THE CONDITION IN OUR COUNTRY

Most women will have a vaginal infection, characterized by discharge, itching, or odor, during their lifetime. The exact population prevalence or incidence is not clearly delineated as majority of patients do not seek any treatment. Many patients use over the counter medications as well as alternative medicines and never report to STD clinics.

III. DIFFERENTIAL DIAGNOSIS

While assessing a patient with vaginal discharge, one needs to rule out

1. Cervicitis
2. Pelvic inflammatory disease
3. Gynecological causes like fistulas, prolapse etc
4. Obstetric causes
5. Mechanical, chemical, allergic, or other noninfectious irritation of the vulva

IV. PREVENTION AND COUNSELING

General measures as applicable to all patients with suspected STIs

- Educate and counsel patient and sex partner(s) regarding RTIs/STIs, genital cancers, safer sex practices and importance of taking complete treatment.
- Treat partner(s) for the suspected organisms.
- Advise sexual abstinence during the course of treatment to minimize transmission.
- Promote the use of barrier contraception like condoms, educate about correct and consistent use.
- Refer for voluntary counseling and testing for HIV, Syphilis and Hepatitis B.
- Consider immunization against Hepatitis B.
- Schedule return visit after 7 days to ensure treatment compliance as well as to see reports of tests done.
- If symptoms persist, assess whether it is due to treatment failure or reinfection and advise prompt referral.

V. OPTIMAL DIAGNOSTIC CRITERIA, INVESTIGATIONS, TREATMENT & REFERRAL CRITERIA

***Situation 1: At Secondary Hospital/ Non-Metro situation: Optimal Standards of Treatment in Situations where technology and resources are limited**

Clinical Diagnosis:

A careful history, examination, and laboratory testing are warranted to determine the etiology

HISTORY should include Information on sexual behavior and practices, menstrual cycles, vaginal hygiene practices (such as douching), and other medications.

EXAMINATION to assess colour, odour, amount (profuse or scanty), character (curdy or thin) of the discharge, associated vulvar abrasions or erosions, urethral meatal discharge and presence or absence of foreign body or IUD thread

Speculum examination can reveal

- White, homogenous discharge, uniformly adherent to vaginal walls with redness of the vaginal walls suggests BV
- White, curdlike discharge seen in candidiasis
- Greenish, frothy discharge seen in trichomoniasis. May also cause strawberry appearance of the cervix.

Investigations:

- Vaginal discharge pH
- Potassium hydroxide (KOH) test
- Wet mount
- Gram stain (considered the gold standard laboratory method for diagnosing BV)
- Culture for yeast- For women with negative wet mounts who are symptomatic. Identifying *Candida* by culture in the absence of symptoms or signs is not an indication for treatment

Treatment:

- Treatment is recommended for symptomatic women to relieve vaginal signs/ symptoms
- Other potential benefits are reduction in the risk of *cervicitis causing organisms*, HIV and other viral STDs.

If there is Vaginitis (TV+BV+Candida)

- Tab. Secnidazole 2gm orally, single dose (Tab. Metoclopramide taken 30 minutes before to prevent gastric intolerance)

OR

- Tab. Tinidazole 500mg orally, twice daily for 5 days

PLUS

- Tab Fluconazole 150mg orally single dose
- OR**
- Clotrimazole 500mg vaginal pessaries once

If Cervicitis

- refer to relevant guidelines

If vaginitis and cervicitis both

- treat for both

Also

- Schedule return visit after 7 days
- Instruct client to avoid douching
- Pregnancy, diabetes, HIV may also be influencing factors (to be considered in recurrent infections)

Management of Sex Partners

- Routine treatment of sex partners is not recommended in cases with VVC or BV.
- Treat current partner only if no improvement after initial treatment
- If partner is symptomatic, treat patient and partner using above protocols
- Advise sexual abstinence during the course of treatment
- Provide condoms, educate about correct and consistent use
- Partners of patients with *T. vaginalis* should be treated with either tinidazole in a single dose of 2 g orally or metronidazole twice a day at 500 mg orally for 7 days.
- For patients with VVC a minority of male sex partners might have balanitis and benefit from treatment with topical antifungal agents

Alternative regimes

For TV or BV (ANY ONE)

- Metronidazole 2 g orally in a single dose
- Metronidazole 500 mg orally twice a day for 7 days
- Tinidazole 2 g orally once daily for 3 days
- Tinidazole 1 g orally once daily for 5 days

- Clindamycin 300 mg orally twice daily for 7 days

For VVC (ANY ONE)

- Miconazole 2% cream 5 g intravaginally for 7 days
- Clotrimazole 1% cream 5 g intravaginally for 7–14 days

Special Considerations

Complicated VVC

A. **Recurrent Vulvovaginal Candidiasis (RVVC):** characterized by four or more episodes of symptomatic VVC in 1 year. Mostly there are no apparent predisposing or underlying conditions. For management

- **Investigations:** Obtain vaginal cultures
- **Treatment:** To maintain clinical and mycologic control

Initial therapy- longer duration of recommended therapy to attempt mycologic remission

- 7–14 days of topical therapy
- 100-mg, 150-mg, or 200-mg oral dose of fluconazole every third day for a total of 3 doses [day 1, 4, and 7]

Maintenance Regime

- Oral fluconazole 100-mg, 150-mg, or 200-mg dose weekly for 6 months
- susceptibility testing is not recommended

B. **Severe VVC:** Characterised by extensive vulvar erythema, edema, excoriation, and fissure formation. Patients treated with short courses of topical or oral therapy are associated with lower clinical response rates in.

- **Treatment with**
 - 7–14 days of topical azole

OR

- 150 mg of fluconazole in two sequential doses (second dose 72 hours after initial dose)

C. Nonalbicans VVC: Optimal treatment options remain unknown.

- Treatment options
 - longer duration of therapy with a non fluconazole azole drug (oral or topical) as first-line therapy.
 - If recurrence occurs, 600 mg of boric acid in a gelatin capsule administered vaginally once daily for 2 weeks.

D. Compromised Host: Includes women with underlying debilitating conditions who do not respond as well

- Treatment
 - Correct modifiable conditions
 - Prolonged (i.e., 7–14 days) conventional antimycotic treatment

Pregnancy

Recommended Regimens for Pregnant Women

In first trimester of pregnancy

- Local treatment with Clotrimazole vaginal pessary/cream only for candidiasis.
- Oral Fluconazole is contraindicated in pregnancy.
- Metronidazole pessaries or cream intravaginally if trichomoniasis or BV is suspected.

In second and third trimester

- oral metronidazole can be given (500 mg orally twice a day for 7 days OR 250 mg orally three times a day for 7 days)

OR

- Tab. Secnidazole 2gm orally, single dose

OR

- Tab. Tinidazole 500mg orally, twice daily for 5 days

HIV Infection

- HIV-positive women- screening for trichomoniasis at entry into care with subsequent screening at least annually is recommended based
- Rescreening 3 months after completion of therapy should be considered among HIV-positive women with trichomoniasis
- Multidose treatment regimen to be considered in HIV-infected women, single doses not effective
- Therapy for VVC in HIV-infected women remains same
- Long-term prophylactic therapy with fluconazole (200 mg weekly) recommended for recurrent VVC with HIV.
- Occurrence of RVVC should not be considered an indication for HIV testing

Referral criteria:

Treatment failure (after excluding reinfection and resistance)

***Situation 2: At Super Specialty Facility in Metro location where higher-end technology is available**

n) Clinical Diagnosis:

Same as above

o) Investigations:

Same as above

In addition, following tests can be done if available

- For TV
 - a. Culture for *T. vaginalis*- sensitive and highly specific commercially available method of diagnosis.
 - b. NAAT
 - c. Nucleic acid probe test to evaluates for *T. vaginalis*, *G. vaginalis*, and *C. albicans*.
- For BV

- a. DNA probe-based test for high concentrations of *G. vaginalis*
 - b. PCR- used in research settings for detection of a variety of organisms associated with BV. Clinical utility is uncertain.
 - c. Culture of *G. vaginalis* not recommended as a diagnostic tool
- For other causes
 - a. PCR assay for detection of gonorrhoea and chlamydial infection, also tests for *T. vaginalis*

p) Treatment:

Same as above

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