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Original Research Article

A study of syndromic and etiological approach for the diagnosis of reproductive tract infections

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ABSTRACT

Background: Reproductive tract infections (RTIs) are one of the most common and major health problem around the world and they are much more widespread in developing countries than in developed countries due to Inadequate health services.

Methods: Detailed history including, menstrual, obstetric and sexual history of the patients were taken and general, physical and local examination was done and clinical symptoms and sign were noted using a structured screening proforma.

Results: In our study syndromic approach has a moderate diagnostic accuracy in detecting vaginal discharge syndrome and pain abdomen syndrome. Syndromic diagnosis is low cost effective, more acceptable and easily available at primary and secondary health centre. It should be continued as first line management.

Conclusions: In present study the vaginal discharge syndrome has sensitivity of 64.71% and specificity of 57.14%, PPV 61.11%, NPV 60.87% and accuracy is 61%. If treatment is given only on the basis of syndromic approach for vaginal discharge syndrome it results in over-treatment in 42.86% (false positive) and under diagnosis in 35.29% (false negative). This approach was found less effective. For lower pain abdomen syndrome the sensitivity is 21.74% and specificity is 84.62%, PPV 38.46%, NPV 70.97% and accuracy is 65.33%. If treatment is given only on the basis of syndromic approach for lower pain abdomen syndrome results in over -treatment in 15.38% (false positive) and under diagnosed 78.26%.(false negative). This approach was found less effective.

Keywords: Reproductive tract infections, Syndromic and etiological approach, Vaginal discharge syndrome

INTRODUCTION

Reproductive tract infections (RTIs) are one of the most common and major health problem around the world and they are much more widespread in developing countries than in developed countries due to Inadequate health services.^[1] These infections cause suffering and distress for both women and men around the world but their consequences are far more devastating and widespread among women than men.^[2,3]

Reproductive tract infections (RTIs) account for the second most important cause for morbidity and mortality

in women of reproductive age due to the lack of medical facilities available. Untreated diseases lead to long term complications- chronic abdominal pain (PID) , ectopic pregnancy, infertility and cervical cancer.¹

Reproductive tract infections is a generic term which includes three types of infection:

Endogenous infections

Infections that result from endogenous overgrowth of organisms normally present in the reproductive tract (Bacterial vaginosis and vulvo-vaginal candidiasis and

other infections).^{4,5}

Iatrogenic infections

Infections caused by poor delivery practices, unsafe abortion, irresponsibly executed pelvic examination, and IUD insertion.^{4,5}

Sexually transmitted infections (STIs)

Sexually transmitted infections are more dynamic than other infections prevailing in the community.^{6,7} In India, bacterial infections such as syphilis, chancroid and gonorrhoea used to be major STIs.^{6,8} Viral agents such as Herpes Simplex Virus (HSV) and Human Papilloma Virus [HPV] are responsible for Genital Herpes, Genital Warts and Cervical Cancer.

Globally, Sexually Transmitted Infections constitute a major public health problem. Prevalence are higher in developing countries where STI treatment are less accessible.^{6,9} Sexually Transmitted Infections (STIs) are infections that are transmitted from one person to another person through sexual contact.^{6,10}

Reproductive tract infections (RTIs) are divided into

- Upper Reproductive Tract Infections (PID) endocervix, uterus, fallopian tube, ovary, and pelvis.
- Lower Reproductive Tract Infections (vulva, vagina, and ectocervix).

METHODS

This prospective study was conducted at Department of Obstetrics and Gynecology in Mahatma Gandhi Medical College and Hospital, Sitapura, Jaipur. Study period was from December 2015 to June 2017.

Method of collection

The ethical committee of Mahatma Gandhi Medical College, Jaipur was informed about the intended work and permission was obtained to conduct the work.

Number of cases

In present study 300 patients attending Gynaecology 2 OPD in MGH during DEC 2015- June 2017 of reproductive tract infections patients and willing to undergo the study were taken. These will be selected based on inclusion and exclusion criteria.

Inclusion criteria

- Women of reproductive age group (20-45 yr)
- women presenting with various symptoms and signs of RTIs (Vaginal discharge, pain in lower abdomen and genital ulcer).

Exclusion criteria

- Patient not given valid consent.
- Unmarried women.
- Women with pregnancy and any uterine pathology.
- Patient with bleeding per vagina.
- Diagnosed genital malignancy.

The angle between the ultrasound beam and direction of blood flow was maintained below 45° for umbilical artery. The umbilical artery was studied in a free loop. Umbilical artery (UA) systolic diastolic ratio >2SD above mean or absent or reversed end diastolic flow in umbilical artery was taken as abnormal. UA PI and UA RI were measured and value >2SD was taken as abnormal. The middle cerebral artery was visualised at the circle of Willis and was insonated soon after its origin from internal carotid artery and the angle of insonation kept close to 0°. The pulsatility index was measured and cerebroumbilical PI ratio calculated. MCA-RI was considered abnormal if measurement was 2 SD below the mean. All the ultrasound evaluations were done by a single obstetrician with expertise in Doppler sonography.

Detailed clinical history

Detailed history including, menstrual, obstetric and sexual history of the patients were taken and general, physical and local examination was done and clinical symptoms and sign were noted using a structured screening proforma. Before proceeding for local examination following things were kept ready:-

One sterilized swab sticks glass test tube for culture and other test tube for other tests.

- Sterilized normal saline.
- 10% KOH.
- Clean and dry glass slides.
- 1ml of normal saline in a vial.
- Narrow range PH stripes.
- A pair of sterilized gloves.
- Pap's smear (liquid base cytology material).
- Unlubricated speculum.
- Glass marking pencil.

The patient was made to lie down in dorsal position. Then local examination was done. Inspection of vulva for edema, congestion, scratch mark or any ulcer, was carried out. Speculum examination was next done - after swabbing the perineum with boiled water (no antiseptic or lubricant was used). Condition of vagina, presence of congestion, petechial hemorrhages on vaginal wall were noted.

Condition of cervix presence of congestion or erosion of cervix, cervicitis, endocervicitis, cervical growth or ulcer were looked for.

1st step was to take culture from posterior fornix of the vagina with sterile swab stick and send for culture and sensitivity. And then PH of vaginal discharge noted by PH strips dipped in vaginal discharge, change in color was noted. Discharge collected on the posterior blade of speculum was taken on the different glass slides for the preparation of different tests (wet mount, KOH mount-whiff test, Gram's staining) and pap's smear taken with help of ayre's spatula. The odour of the discharge was noted and also did whiff test (bacterial vaginosis), and types of color and nature of discharge also noted.

Internal examination (per vaginal) was done to find out the size, shape of uterus and rule out the tenderness and masses in the fornix and all patients underwent USG to rule out the pelvic pathology.

RESULTS

The Present study on syndromic and etiological approach for diagnosis of reproductive tract infections was conducted on 300 gynae patients of reproductive age group (20-45yrs) attending the gynecology OPD at Mahatma Gandhi Medical College and Hospital.

Table 1: Distribution of the cases according to chief complains.

Chief complain*	Number	Percentage
Vaginal Discharge	296	98.67
Pain lower abdomen	120	40.00
Pruritus vulva	60	20.00
Dyspareunia	54	18.00
Foul smelling	4	1.33

The mean age of the study group was 31.5±6.085 yrs. Majority were between 31 to 40 years of age (48.33%).

Table 2: Distribution of the cases according to per speculum findings (syndromic).

Per speculum	Number	Percentage
Normal	97	32.33
Thin watery discharge	117	39.00
Thick curdy white discharge	79	26.33
Green frothy discharge foul smelling	7	2.33
Total	300	100

RTIs were more common in Rural women than urban (60% vs 40%).

Majority (95%) of them were married. very few were widow or divorcee.

Most of them belonged to lower middle class (43.67%) followed by upper middle class (22%) as per Kuppaswamy socioeconomic status classification.

Table 3: Distribution of the cases according to Per vaginal findings (syndromic).

	Number	Percentage
Normal	249	83.00
Ut. bulky, Tenderness in fornix	21	7.00
Ut. N size, Tenderness in fornix	31	10.00
Total	300	100

Table 4: Distribution of the cases according to whiff test (Etiological).

Whiff test	Number	Percentage
Negative	217	72.33
Positive	83	27.67
Total	300	100

Most common Chief Complain reported was abnormal vaginal discharge 96.33% in present study. Lower abdominal pain was present in 40% of cases whereas itching were present in 20% cases while 18.67% were reported with complains of dyspareunia.

Table 5: Distribution of the cases according to wet mount (Etiological).

Wet mount	Number	Percentage
Normal	147	49.00
Hyphae and Pseudo	75	25.00
Hyphae seen		
Clue cells seen	69	23.00
Flagellated protozoa seen	9	3.00
Total	300	100

Gram staining was found Normal in 217 (72.33%) cases, pus cells, gram positive bacteria were seen in 13.67% cases. Pus cells, gram negative bacteria were seen in 14% cases.

Table 6: Distribution of the cases according to gram staining (Etiological).

Gram staining	Number	Percentage
Normal	217	72.33
Pus cells, gram positive bacteria seen	41	13.67
Pus cells, gram negative bacteria seen	42	14.00
Total	300	100

Out of 300 cases In ELISA test, HBs Ag was positive in 9(3%) cases, VDRL positive cases were in 1.67% and HIV positive were 0.67% cases.

Out of 300 cases in 186(62%) cases pap smears were reported normal, 32.33% cases were inflammatory, 2% bacterial vaginosis, 2.33% candidiasis, 0.67%

trichomoniasis and 0.67% were low grade squamous epithelial lesion (LSIL).

Table 7: Distribution of the cases according to vaginal swab culture (Etiological).

Vaginal swab culture	Number (N=300)	Percentage
Normal	210	70.00
candida spp.	81	27.00
Trichomoniasis	9	3.00
Total	300	100

Per vaginal findings were normal in 83% cases. Tenderness were present in 17%.

Table 8: Distribution of the cases according to Elisa Test.

ELISA Test	Number (N=300)	Percentage
HbsAg	9	3.00
VDRL	5	1.67
HIV	2	0.67

On the basis of etiological diagnosis out of 300 cases 147 (49%) cases were normal, Bacterial vaginosis was diagnosed in 21% cases, candidiasis was observed in 20.33%, 6.67% cases had mixed infection and 3% were of Trichomonas.

Table 9: Distribution of the cases according to Pap Smear.

Pap smear	Number	Percentage
Normal	186	62.00
Inflammatory	97	32.33
Inflammatory, bacterial vaginosis	6	2.00
Inflammatory, candidiasis	7	2.33
Inflammatory, trichomoniasis	2	0.67
low grade squamous epithelial lesion (LSIL)	2	0.67
Total	300	100

On the basis of syndromic diagnosis Out of 300 cases most commonly diagnosed syndromes was vaginal discharge syndrome (54%) followed by lower abdominal pain syndrome (17.33%). No cases of genital ulcers and genital warts were reported.

Table 13: Diagnostic statistics of Vaginal discharge syndrome (VDS) considering the etiological diagnosis.

Syndromic Diagnosis	VDS	Present No. (%)	Absent No. (%)	Total No. (%)
	Present	99 (64.71%) (Sensitivity)	63 (42.86%)	162 (54%)
Absent	54 (35.29%)	84 (57.14%) Specificity	138 (46%)	
Total	153 (100%)	147 (100%)	300 (100%)	

In the present study, 162 (54%) of women positive for Vaginal discharge syndrome. However Syndromic discharge (VDS) correlated poorly with laboratory evidence of RTIs, with sensitivity of 64.71% and specificity of 57.14% PPV 61.11% and NPV was 60.87% with accuracy 61%.

Table 10: Distribution of the cases according to syndromic diagnosis.

Syndromic	Number	Percentage
Normal	86	28.67
Vaginal discharge syndrome (VDS)	162	54.00
Lower Pain Abdomen Syndrome	52	17.33
Genital warts	0	0.00
Genital Ulcers	0	0.00
Total	300	100

Table 11: Distribution of the cases according to final (etiological) diagnosis.

Etiological diagnosis	Number	Percentage
Normal	147	49.00
Bacterial	63	21.00
Candidiasis	61	20.33
Mixed infection	20	6.67
Trichomonas	9	3.00
Total	300	100

Table 12: Association of syndromic and etiological diagnosis.

Syndromic and etiological diagnosis	Normal No. (%)	lower pain abdomen syndrome No. (%)	VDS No. (%)
Normal	53 (61.63%)	31 (59.62%)	63 (38.89%)
Bacterial vaginosis	21 (24.42%)	15 (28.85%)	27 (16.67%)
candidiasis	7 (8.14%)	1 (1.92%)	53 (32.72%)
Mixed infection	5 (5.81%)	3 (5.77%)	12 (7.41%)
Trichomonas	0 (0%)	2 (3.85%)	7 (4.32%)
Total	86 (100%)	52 (100%)	162 (100%)

In the present study, 52 (17.33%) of women positive for Lower Pain Abdomen Syndrome. However, correlated

poorly with laboratory evidence of RTIs, with sensitivity of 21.74% and specificity of 84.62% PPV 38.46% and NPV was 70.97% with accuracy 65.33%.

Table 14: Diagnostic statistics of Syndromic (Lower Pain Abdomen Syndrome) considering the etiological diagnosis.

	Lower Pain Abdomen Syndrome	Present No (%)	Absent No (%)	Total No (%)
Syndromic diagnosis	Present	20 (21.74%) (Sensitivity)	32 (15.38%)	52 (17.33%)
	Absent	72 (78.26%)	176 (84.62%) (specificity)	248 (82.67%)
	Total	92 (100%)	208 (100%)	300 (100%)

Table 15: Comparative statistics of syndromes.

	Vaginal discharge syndrome (VDS) %	Lower Pain Abdomen Syndrome%
Sensitivity	64.71%	21.74%
Specificity	57.14%	84.62%
PPV	61.11%	38.46%
NPV	60.87%	70.97%
Accuracy	61%	65.33%

DISCUSSION

Reproductive tract infections are most common gynecological complaint among women in reproductive age group.

The study was conducted on 300 women of reproductive age group (20-45 yr) attending the gynecology OPD during December 2015 to June 2017 at Mahatma Gandhi Medical College and Hospital who fulfilled the eligibility criteria. After taking Detailed menstrual, obstetric and sexual history of the patients and General, physical and local examination and investigation were done. Then considering Etiological Diagnosis as gold standard method comparison of sensitivity and specificity of syndromes were calculated.

Distribution of age group

The mean age of the study group was 31.52±6.085 (20 to 45) yrs out of which 145 patients (48.33%) were in the age group of 31-40yrs, While 43% in age group of 20-30yr and 8.67% in age group of 41-50 yrs. The same age group was studied by Aggarwal P et al. In his study he showed that majority of patients were between the age group of 31 to 40 years (36.3%).¹² Distribution of patient according to Sociodemographic status. In present study most of the patients 180(60%) belong to rural area and while 120(40%) patients were from urban area. The present study showed that the rural women suffer more than urban (60% vs 40%) from reproductive tract infection.

Ray K et al showed in their study that reproductive tract infections were more common in rural women than urban population.¹²

Distribution of patient according to marital status

In present study Out of 300 patients 285 (95%) patients were married, while 4% were divorcee, while only 1% widow had the complaints of reproductive tract infection.

Bohra et al carried out similar study in Nepal mentioned that symptoms related to RTIs was common in young married women.¹³

Distribution of patients according to education

In present study analysis out of 300 cases 31.67 % were educated till secondary, 20% were having primary education, 15.33% were Illiterate were and higher education holder were 17.67%.

Ghebremichael M et al showed in their study that majority of study participants had pre-secondary education (77%).¹⁴

Distribution of patients according to socio economic status

In present study as per kuppuswamy classification of socio economic status maximum no. of patients 131(43.67%) were lower middle class, while 22% patients were upper middle class,13% patients were lower class and 14.67% were upper class and 6.67% patients were upper lower class. Bote MM et al in their study that More than half of women were from higher socioeconomic status.¹⁵

Distribution according to religion

274 (91.33%) patients were Hindu, while 8% were muslim and only 0.67% were Sikh. Majority of my patients are Hindu because nearby area is Hindu

dominated. Bote MM et al in their study 76.4% were muslim, 20.2% were Hindu and 3.4% were others.¹⁵

Parity

In present study distribution according to parity of patient revealed that Maximum no. of patients 99 (33%) were para 2 and 68 (22.67%) patients were primipara, while 14% patients had no children (nulliparous) and 30.33% patients were multiparous women (>P3).

Romoren et al in their study showed maximum no. of patient 243 (35%) were primiparous.¹⁶

Distribution of patient according chief complain (symptoms)

In present study, out of 300 patients 296 (98.67%) presented with vaginal discharge. while 40% patients had pain in lower abdomen, 20% patient with pruritus vulva, 18% patient with dyspareunia and 1.33% patients presented with foul smelling vaginal discharge.

Hawkes et al in their study 94% women reported with abnormal vaginal discharge, 40% reported with lower abdominal pain, 55% were having genital itching and genital ulceration was present in 1% of cases.¹⁷

Distribution of patient according Per Speculum examination

In present study analysis of patients according to findings of per speculum examination out of 300 patients 97 (32.33%) had normal vaginal discharge while 117 (39%) presented with excessive homogenous thin watery discharge, 79 (26.33%) patient had thick curdy white discharge. 7 (2.33%) patient had green frothy discharge with foul smell. Shethwala N et al showed in their study that most of patients presented with Homogenous white discharge 43(28.7%) cases, 42(28%) presented with curdy white discharge.¹⁸

Per vaginal examination

In present study analysis of patients according per vaginal examination out of 300 cases 249 (83%) were normal, 10.00% cases presented with Normal size uterus and tenderness in fornix and 7% cases presented with bulky uterus and tenderness in fornix. Fornicial Tenderness was present in cases 17%. Ray K et al in their study lower abdominal tenderness was observed in 13.5% of women.¹¹

Whiff test finding

Out of 300 cases whiff test were positive in 83(27.67%) cases and negative in 217 (72.33%) cases. Whiff test confirmation of bacterial vaginosis if fishy smell present then whiff test positive

Wet mount finding

According to wet mount findings were Normal in 147 (49%) cases, Hyphae and Pseudo Hyphae seen in 25.00% cases, Clue cells seen in 23% cases While Flagellated protozoa seen in 3% cases.

Swab culture finding

Out of 300 cases Most of the cases 210(70%) were sterile on vaginal swab culture. candida species were present in 27% cases while Trichomoniasis were present in 3% cases. Swab culture is Confirmatory diagnosis of candida and trichomonas. Vasantha PL et al in their study whiff test, wet mount and vaginal swab culture showed by laboratory diagnosis which was 52%.¹⁹

Gram staining finding

In present study out of 300 patients gram staining was found Normal in 211 (72.33%) cases, pus cells, gram positive bacteria were seen in 13.67 % cases. Pus cells, gram negative bacteria were seen in 14% cases.

Gram staining is confirmatory diagnosis of bacterial vaginosis and diagnosis for gram positive and gram negative bacteria. Bohara et al found in their study that thirteen percent had trichomoniasis and 7% had gonorrhoea identified in Gram stained smears and cultures.¹³

ELISA test finding

In present study Out of 300 cases In ELISA test, HbsAg was positive in 9 (3%) cases, VDRL positive cases were in 1.67% and HIV positive were 0.67% cases. Aggarwal P et al only two women were HIV positive ; one showed VDRL reactivity, though the VDRL titre was low (1:4), she was also reactive by TPHA test.²⁰

Pap smear finding

In present study on pap smear finding, out of 300 cases 186 (62%) cases were reported normal, 32.33% cases were inflammatory, 2% bacterial vaginosis, 2.33% candidiasis, 0.67% trichomoniasis and 0.67% were low grade squamous epithelial lesion (LSIL). Prabha MLS et al Pap smear showed 32.9% inflammatory changes and 0.25% lowgrade squamous intraepithelial lesion.²¹

Syndromic diagnosis

In present study Out of 300 cases most commonly diagnosed syndromes was vaginal discharge syndrome (54.00%) followed by lower abdominal pain syndrome (17.33%). No cases of genital ulcers and genital warts were reported.

Prabha MLS et al prevalence of reproductive tract infections/sexually transmitted infections by syndromic

diagnosis was 61.9%.²¹ The most common syndromes diagnosed is vaginal discharge syndrome (34%) followed by lower abdominal pain syndrome (28%). No cases of genital ulcers and genital warts were reported.

Etiological finding

In present study analysis of patients on Etiological diagnosis, out of 300 cases 147 (49%) cases were normal, Bacterial vaginosis was diagnosed in 21% cases, candidiasis was observed in 20.33%, 6.67% cases had mixed infection and 3% were of trichomonas. Patnaik et al The most commonly infections identified by laboratory diagnosis was bacterial vaginosis (14.3%).²²

Sensitivity and specificity of vaginal discharge syndrome

In present study for the sensitivity analysis to compare the different diagnostic methods for RTI/STI etiological diagnosis was considered as gold standard method. In the present study, out of total 300 patients 162 (54%) of women were positive for VDS. However Vaginal discharge syndrome(VDS) correlated poorly with laboratory evidence of RTIs, with sensitivity of 64.71% and specificity of 57.14% PPV 61.11 % and NPV was 60.87 % with accuracy 61%. Prabha et al in this study vaginal discharge syndrome sensitivity was 58.95% and specificity was 55.13%, PPV was 28.57% and NPV was 81.52%.¹²

Sensitivity and specificity of lower abdominal pain syndrome

In the present study, 52 (17.33%) of women positive for Lower Pain Abdomen Syndrome. However, correlated poorly with laboratory evidence of RTIs, with sensitivity of 21.74% and specificity of 84.62% PPV 38.46% and NPV was 70.97% with accuracy 65.33%.

Prabha et al showed lower abdominal pain syndrome sensitivity is very low (14.49%) and high specificity 76.63%, PPV is 11.24% and NPV is 81.44%.¹²

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