



Evaluation of Efficacy of Herbal Cream for Senile V- A Pilot Study

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ABSTRACT

Inspit of having a great treasure of useful drugs, Unani medicines are not so popular in medical world due to many reasons includind lake of scientific evaluation and drug standardization. In that connection we put a Unani formulation in the form of cream for clinical trial for the common compliant of vaginal dryness during menopause. It is the most common problem females are facing today. Cream contains Aliwa, Roghn-e-Zaitoon, Roghan-e-Karanj and Post-e-Amaltas. The cream was applied locally in the vagina daily at bed time for seven nights. The patients were kept under observation and improvement was recorded in each alternate days follow up. The result was very encouraging as near about all patients were found satisfactory relief without any complication.

Key Words: Aliwa (*Aloe vera*) Roghan-e-Karanj(*Karanj oil*) Post-e-Amaltas (*Bark of Cassia fistula*) Roghan-e-Zaitoon(*Olive oil*)

1. INTRODUCTION OF VIGINAL INFECTION, (VAGINITIS)

- 1) VULVOVAGINITIS IN CHILDHOOD.
- 2) TRICHOMONIASIS.
- 3) MONILIASIS.
- 4) VAGINITIS DUE TO CHLAMYDIA TRACHOMATIS.
- 5) ATROPHIC VAGINITIS.
- 6) NON-SPECIFIC VAGINITIS.
- 7) TOXIC SHOCK SYNDROME

ATROPHIC VAGINITIS (SENILE VAGINITIS)

Vaginitis in postmenopausal women is called atrophic vaginitis. The term is preferable to senile vaginitis. There is atrophy of the vulvovaginal structures due to estrogen deficiency. The vaginal defence is lost. Vaginal mucosa is thin and is more susceptible to infection and trauma. There may be desquamation of the vaginal epithelium which may lead to formation of adhesions and bands between the walls.

Clinical Features

1. Virginal discharge:

Postmenopausal women: In postmenopausal women, atrophic vaginitis is a common cause. Other causes of discharge include vaginal cancer, cervical cancer, and endometrial cancer and, in women who are incontinent or bedbound, chemical vulvitis.

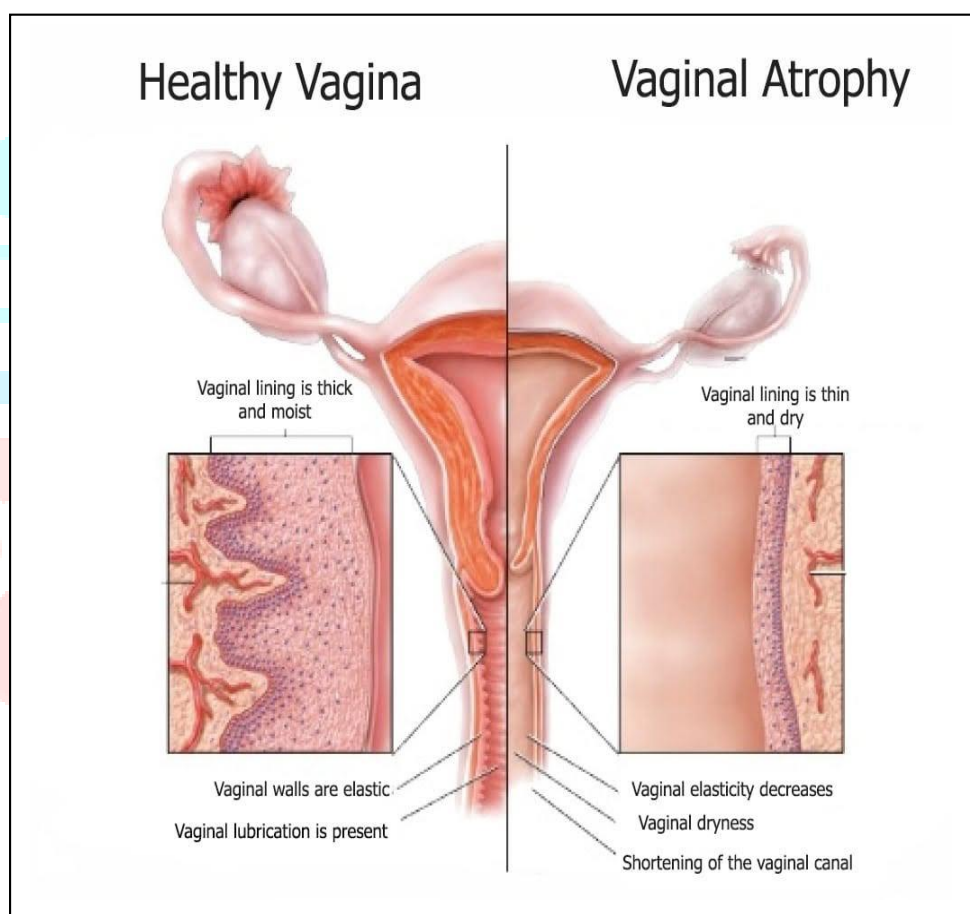


Fig. Virginal Atrophy

1. Symptoms of Viginal Pain:

Vaginal pain can have many different characteristics. Describing the pain in detail can help a healthcare provider correctly diagnose the problem. Below are the most common types of vaginal pain:

- A. **Burning:** Vaginal yeast infections, BV, and other types of infection often cause a burning sensation, especially during or after intercourse. Vulvodynia also often causes burning pain, though this typically occurs alongside other symptoms.
- B. **Itching:** Itchiness is a classic sign of an infection, such as a yeast infection, BV, or an STI. Less frequently, a pelvic floor injury causes nerve dysfunction that feels like itchiness or another unusual sensation. Some people experience vaginal itchiness specifically during intercourse. Some possible causes of this include:
 - Vulvodynia
 - The rupture of a Bartholin's cyst
 - Healing following a physical injury
- C. **Tension or muscle spasms:** Tightness, soreness, and muscle spasms in the vagina may indicate pelvic floor dysfunction. Some people also experience pain with different characteristics or in other areas, for example, they may have lower back pain or hip discomfort. Vulvodynia can cause the vaginal muscles to tense before or during intercourse. Some people report that their muscles tense so forcefully that they are unable to have intercourse.
- D. **Tenderness or sensitivity:** If the skin around the vagina and vulva feels painful, tender, or sensitive, this may be a symptom of a Bartholin's cyst. The area may also be discolored, and there may be a hard lump or visible swelling. If an infection develops, the pain may become intense. Trauma to the vagina or vulva can also cause tenderness and sensitivity. Many people report soreness after giving birth, especially following a perineal tear.
- E. **Pain during intercourse:** Intercourse can make any type of vaginal pain worse because friction causes irritation. However, if a person only experiences vaginal pain during intercourse, vulvodynia may be the cause.

If a fishy odor follows painful intercourse, this could indicate BV.

3. Dyspareunia

Dyspareunia is a common and troubling complaint of women with vulvodynia, and in particular provoked vestibulodynia. Painful sex can also result from a range of conditions causing genital pain, including vulval skin conditions (e.g. lichen sclerosus), vulvovaginal and urinary tract infections, sexually transmitted infections (STIs) and endometriosis. Dyspareunia is often co-morbid with sexual difficulties such as lack of desire and arousal, and strain within the sexual relationship. Psychosocial correlates include negative body image, catastrophising, hypervigilance to pain, depression and anxiety, and low self-esteem. Although these psychosocial variables may be both aetiological and



Fig. 5 Painful intercourse



Fig. 6 Dyspareunia

sequelae, the cross-sectional nature of most studies limits understanding of causal direction. To date, most research on painful sex has been based on small clinical samples. These studies exclude women who are not sought help and are therefore not representative of the general population. Community surveys are limited, as are studies that investigate medical and psychosocial factors simultaneously. Specific subgroups, such as adolescent women, have also received little focused research attention.

4. Vaginal discomfort

Some vaginal discharge is normal, particularly when estrogen levels are high. Estrogen levels are high in the following situations:

- A few days before ovulation
- During the first 2 weeks of life (because maternal estrogens are transferred before birth)
- During the few months before menarche and during pregnancy (when estrogen production increases)
- With use of drugs that contain estrogen or that increase estrogen production (eg, some fertility drugs)

However, irritation, burning, and pruritus are never normal. Normally in women of reproductive age, *Lactobacillus* species is the predominant constituent of normal vaginal flora. Colonization by these bacteria keeps vaginal pH in the normal range (3.8 to 4.2), thereby preventing overgrowth of pathogenic bacteria. Also, high estrogen levels maintain vaginal thickness, bolstering local defenses. Factors that predispose to overgrowth of bacterial vaginal pathogens include

- Use of antibiotics (which may decrease lactobacilli)
- Alkaline vaginal pH due to menstrual blood, semen, or a decrease in lactobacilli
- Poor hygiene
- Frequent douching
- Pregnancy
- Diabetes mellitus

- An intravaginal foreign body (eg, a forgotten tampon or vaginal pessary)

The most common causes of vaginal itching and discharge vary by patient age (see table Some Causes of Vaginal Pruritus and Discharge).

II. Importance of Herbs used for various Viginal Infections:

A. Pongamia oil for fighting bacterial and fungal infections

Pongamia pinnata (Linn.), popularly known as Karanja or Indian Beech, is a medicinal plant known for its multitude of benefits. Its seeds contain about 28-34% oil with a high percentage of polyunsaturated fatty acids. Pongamia is rich in phenylated flavonoids. Pongamia seed oil contains a bioactive molecule known as karanjin. Six compounds (two sterols, three sterol derivatives and one disaccharide) and eight fatty acids (three saturated and five unsaturated)



Fig. 9 Karanja leaf and oil



Fig.10 Olive oil fruits

B. Olive Oil:

Olive is a tree. People use the oil from the fruit and seeds, water extracts of the fruit, and the leaves to make medicine. Olive oil is most commonly used for heart disease, high cholesterol, and high blood pressure. In foods, olive oil is used as a cooking and salad oil. Olive oil is classified, in part, according to acid content, measured as free oleic acid. Extra virgin olive oil contains a maximum of 1% free oleic acid, virgin olive oil contains 2%, and ordinary olive oil contains 3.3%. Unrefined olive oils with more than 3.3% free oleic acid are considered "unfit for human consumption." Fatty acids in olive oil seem to decrease cholesterol levels and have anti-inflammatory effects. Olive leaf and olive oil might lower blood pressure. Olive might also be able to kill microbes, such as bacteria and fungus.

C. Post-e-Amaltas (*Bark of Cassia fistula*)

Famed as the “Golden Rain Tree” owing to its beautiful hanging yellow flowers, Amaltas has umpteen health benefits. Be it the fruit pulp, leaves, roots or flowers, Ayurveda signifies this plant as



Fig. 11 Almaltas leafs



Fig. 12 Alovera in V infection

“Sarvarogaprashamani” one that cures all types of diseases and shields the body against numerous microbial infections. The abundance of bioactive ingredients and strong purgative, carminative, anti-pruritic and anti-inflammatory properties offer relief from constipation, common cold, intestinal and skin disorders, boosts immunity, promotes cardiac functioning, treats wounds, cures dyspepsia, prevents flatulence, inflammation and also manages diabetes. Amaltas is widely used in almost all ayurvedic formulations that are directed towards boosting overall immunity. Apart from alleviating different types of infections, the ornamental herb also provides a traditional remedy for boosting digestion, improving metabolism, improving cardiac functions, remedying digestive troubles and treating wounds. Be it blood disorders, skin diseases, loss of appetite, urinary anomalies, gout or constipation, this extremely powerful herb provides a striking remedy for all. The collection of biochemical compounds present in this herb has been used since ancient times to battle germs and shield the body against various infections. Thanks to its strong anti-microbial properties, amaltas is not only used for removing bacteria or germs from the body but also used for treating and healing wounds. It is also extremely effective in reducing general debility, weakness, fatigue and improving the vitality of the body.

D. Alovera against antifungal activity in Viginal infection.

Aloe vera contains antifungal properties that are beneficial for reducing the symptoms of vaginal infections. Aloe vera gel can soothe dry and inflamed skin around the vaginal area. The gel can also help reduce itching and burning associated with vaginal infection. Extract the aloe vera gel from the aloe vera leaf or use 100% aloe vera gel found in drug stores. With the help of cotton, apply aloe vera gel directly on the outside of the vagina. Leave it for 10 minutes and then wash it off with cold water.

III. AIMS & OBJECTIVES:

- Vaginal dryness is a most common and disturbing problems during menopausal period so it seemed necessary to pay an attention towards these disorders in the light of Unani system.
- Therefore an attempt has made to do the complete clinical study and to observe the effect of this Unani formulation for treatment, and also in preventing reoccurrence.
- This study also aim to find out whether any complications of the medicine or the recurrence after cure.
- To provide cost effective therapy and popularize the Unani Medicine by proving this cream formulation.

IV. MATERIAL AND METHODS:

Total 15 patients with complain of vaginal dryness, itching, irritation, and/or pain with sexual intercourse (known as dyspareunia), vaginal discomfort during menopause are confirmed with the clinical diagnosis were selected from the outpatient department of Amraz-e-Niswan-wa-Atfal of Dr. M.I. J. T. Unani Medical College and Hospital. Out of 18 patients 15 patients came for follow up and got the treatment, but other 02 patients failed to return for follow up. It is possible that these women had persistent disease and sought additional care elsewhere and therefore did not bother to return.

Selection Criteria

The criterion for selection of the patients in this study chiefly was depends upon patient's chief complains. Each woman was interrogated, physical examination and pelvic examination was done.

Chief complains

1. Pruritus Vulvae
2. Vaginal Irritation
3. Dyspareunia
4. Vaginal discomfort

Exclusion criteria

Following patients were excluded from the study,

- Genital tuberculosis
- Young patients with active gonads
- Any genital malignancy
- HIV positive patients
- The patients who were not ready for giving consent and not co-operating for examination.

Selection of Formulation

The drugs selected for clinical trial after a deep study of VAGINAL DRYNESS and its management. The cream is formulated on the basis of recent known study and analysis of the drug which are having soothing, lubricating and estrogenic activity.

Ingredients

Aliwa	25gm
Roghan-e-Zaitoon	25gm
Roghan-e-Karanj	25gm
Post-e-Amaltas	25gm

Method of preparation

All the above drugs are purchased from local market. Post-e-Amaltas was crushed and fine powdered. Aliwa and Post-e-Amaltas powder was mixed with Roghan-e-Karanj and Roghan-e-Zaitoon and amalgamated to achieve a cream.

Method of administration

Cream was applied twice a day per vaginally at least for seven days.

V. OBSERVATIONS AND RESULTS

Table: 1- Age group of the Patient

S. No	Age Group	No. of Patient	Sexually active	%
1	35-45	5	5	33.33%
2	46-55	7	6	46.66%
3	56-65	3	0	20.00%
Total Sexually activeness		15	11	73.33%

Chart-Showing Age group of the Patient complaining of the symptoms

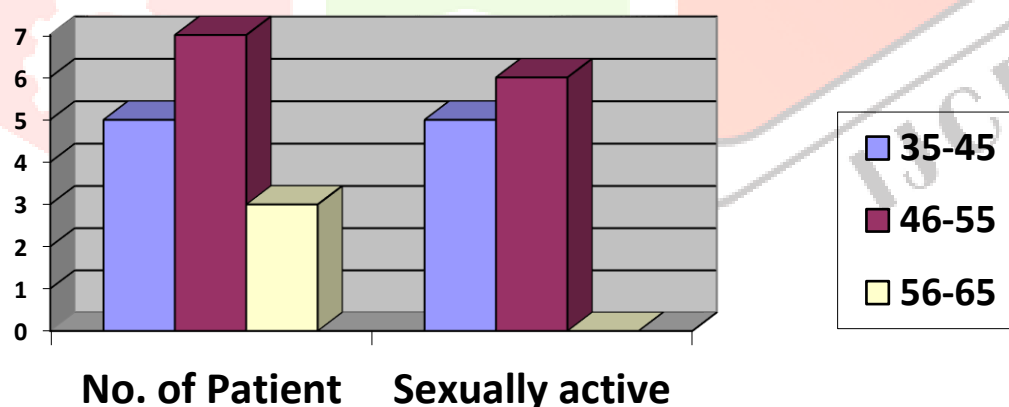


Table-Showing the symptoms before and after treatment

Sr. No	Symptoms	Before treatment	After treatment	Percentage of response
1	Pruritus Vulvae	13	0	100%
2	Irritation	13	3	76.92 %
3	Dyspareunia	11	2	81.81 %
4	vaginal discomfort	15	0	100%

Chart-Showing the symptoms before and after treatment

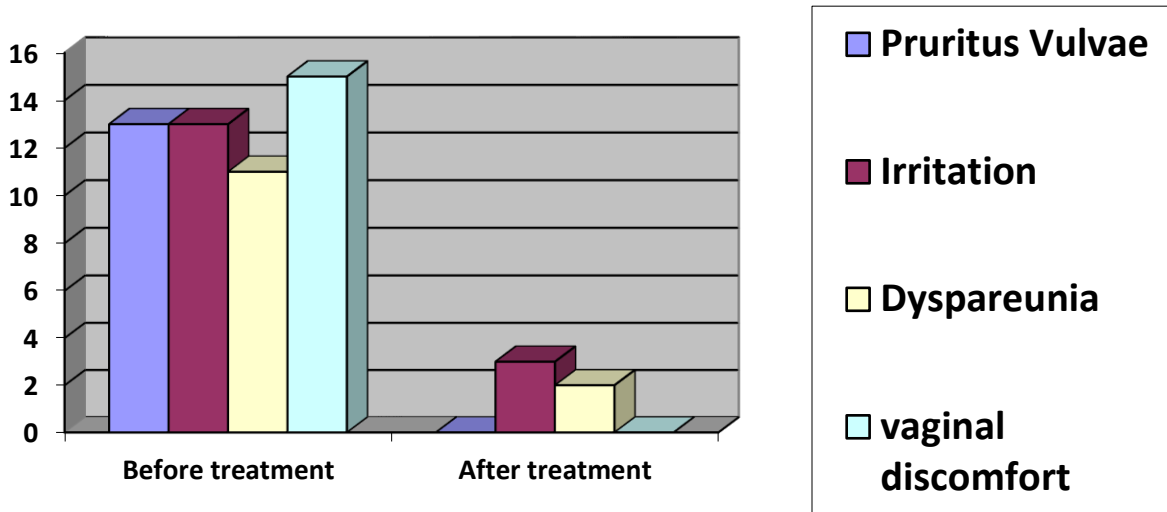


Table-Showing other symptoms before and after treatment

Sr. No	Symptoms	No of Patient Before treatment	No of Patient After treatment	% Result
1	Hot flashes	13	11	15.38%
2	Mood Changes	12	05	58.33 %
3	Night sweats	15	15	00%
4	Urinary tract infections	08	05	37.50%

Chart-Showing other symptoms before and after treatment

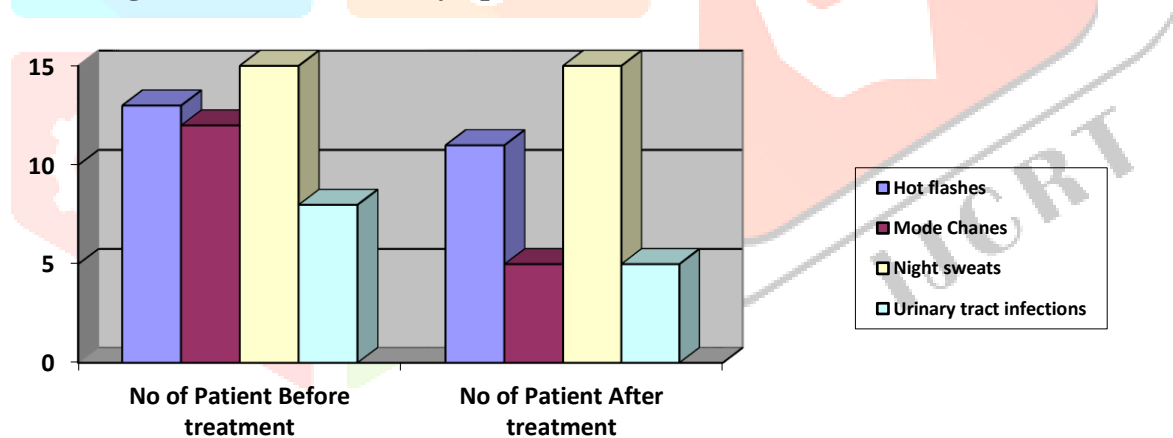
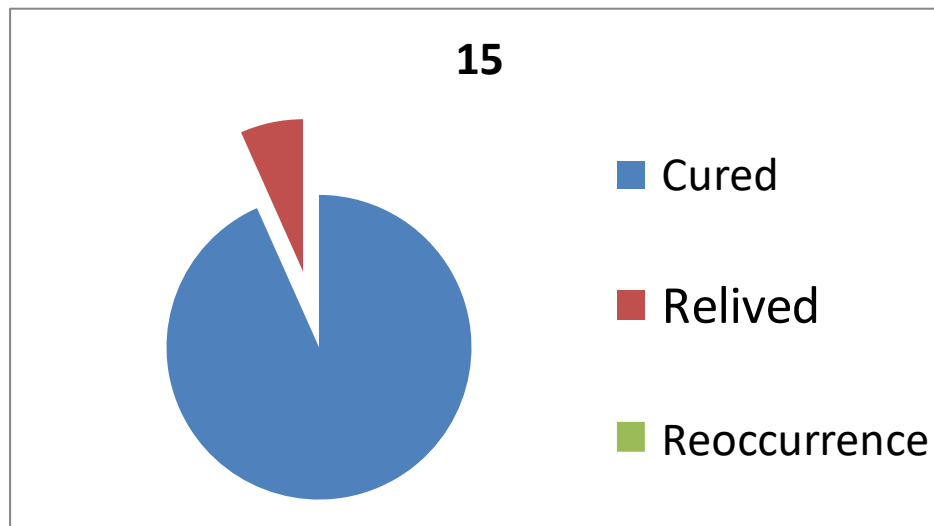


Table showing the percentage of drug response

No of cases	Cured	Relived	Reoccurrence
15	14	01	00%
Percentage	93.33%	6.66%	00%

Chart showing the percentage of drug response**V. DISCUSSION AND CONCLUSION**

In this study 18 cases of VAGINAL DRYNESS in age group of 35 to 65 years were selected from the outpatient department of Amraz-e-Niswan-wa-Atfal of Dr. M.I. J. T. Unani Medical College and Hospital.

During our work we found that the most of the patients were belong to the age group of 46-55 years i.e. 46.66% of all cases and near of 73.33% of all were sexually active.

The maximum number of cases had Pruritus vulvae, Irritation, Dyspaurnia and vaginal discomfort and after treatment Pruritus was disappear in all cases i.e. 100% achievement. Vaginal discomfort was completely disappear in all patient i.e. also 100% achievement and there were 11 patient complains pain during sexual intercourse out 11 patient 9 were found completely relief fir that after treatment that is 86.66% result and irritation was subsided in 10 out of 13 patient i.e. 76.92% achievement. Some of the other symptoms were observed and calculated statistically and tabulated systematically on examination the most frequent complaint by the patient was Night sweats near about all cases but there were no any responses of our cream towards that complain. Other was Hot flashes about 13 out of 15 patient were complain for that but after treatment it is found that the only 2 patient say satisfactory relief towards this i.e. is 15.38% achievement. 08 patients were complaining for UTI and out of 8 patient 05 patients were get cure from the said complain. Mood changes were found in 12 patient and 05 were found no complain after treatment.

In addition efficacy and potency of the formulation it was observed that the formulation caused no any adverse effect and complication in the patients, which proves its safety also.

CONCLUSION:

After this research work we were concluded following points,

1. Vaginal dryness is more prevalent in Menopausal women.
 2. The patients of age group 46-55 years are facing more hurdles towards this problem.
 3. There were no any influences of seasons as well as diet present.
 4. The chief complain were Pruritus vulvae, vaginal discomfort, Dyspareunia and irritation.
 5. Other complains which were most important were Hot flashes, Mood changes, Night sweats and Urinary tract infection.
 6. The drug was found more effective and beneficial easily to available.
 7. Analysis of all constituent of the formulations showed Soothing, lubricant, estrogenic, anti-inflammatory, anti-bacterial, anti-fungal, hormone mimicking activity.
 8. The overall drug response to the treatment was satisfactory and encouraging.
 9. There were no any adverse effects were noticed and no any Side effects were complained by patient.
- The drug was mentioned safe and useful in VAGINAL DRYNESS. It was a step in progress of study further detail scientific evaluation is needed on the basis of this study in futures to establish proper efficacy of this Unani remedy in VAGINAL DRYNESS.

Bibliography

1. Dawn C,S Text Book of Obstetrics and Neonatolog, 11th edition 1990
2. David mckay jane Norman, Gynaecology Edition 2000
3. Rock A. Johan, John D.Thompson, Telinds opretive Gynaecology, 8th edition 1997
4. PDR for Herbal Medicine 3rd edition Published by Thomson PDR at Montvalve.
5. Cyclopedia of Estern Medicine, Khazain-ul-Advia-Alama Hkm Najmul Ghani Rampuri, published by Indra Kitab-ul-Shifa Darya Ganj New Delhi.
6. Pharmacographia Indica A history of the Principal Drugs of Vegetable origin Published by William dymock, CJH warden david Hooper, Low price publications. New Delhi.
7. Robert W.Shaw. Gyneacology 3rd edition 2003 Binik YM. Should dyspareunia be retained as a sexual dysfunction in DSM-V? A painful classification decision. Arch Sex Behav 2005;34:11–21.
8. Schultz W, Basson R, Binik Y, Eschenbach D, Wesselmann U, Van Lankveld J. Women's sexual pain and its management. J Sex Med 2005;2:301–16.
9. Harlow BL, Kunitz CG, Nguyen RH, Rydell SA, Turner RM, MacLehose RF. Prevalence of symptoms consistent with a diagnosis of vulvodynia: population-based estimates from 2 geographic regions. Am J Obstet Gynecol 2014;210:40. e1–40. e8.
10. D.C. data Textbook of Gynecology 6th edition Chapter 12 Infections of the Individual Pelvic Organs page no 165
11. Hayes RD. The prevalence of dyspareunia. In Goldstein AT, Pukall CGI, editors. Female Sexual Pain Disorders. Evaluation and Management. Chichester: Wiley-Blackwell; 2009. pp. 4–8.
12. Bachmann GA, Rosen R, Arnold LD, Burd I, Rhoads GG, Leiblum SR, et al. Chronic vulvar and gynecologic pain: Prevalence and characteristics in a self-reported survey. J Reprod Med 2006;51:3–9.
13. Al-Abbadey M, Lioffi C, Curran N, Schoth DE, Graham CA. Treatment of female sexual pain disorders: a systematic review. Jex Marital Ther 2016;42:99–142.