

**Summer Training at
Bharat Serum and Vaccines Pvt. Ltd., Mumbai
(April 3 to June 2, 2017)**

Study on Naturopathy in Gynecology Segment

**By
Garima Kumari**

**Under the guidance of
Dr. Ashok Peepliwal**

**MBA Pharmaceutical Management
2016-2018**

 **IIHMR UNIVERSITY**
School of Pharmaceutical Management
**The IIHMR University, Jaipur
2017**

CERTIFICATE

This is to certify that **Ms. Garima Kumari** has undergone summer training in **Bharat Serum and Vaccines Pvt. Ltd.** from 3rd April to 2nd June 2017.

The candidate herself completed the project assign to her during summer training. Her approach to the project was sincere and proactive. This summer training is in partial fulfillment of the course requirement recommended for the award of MBA in Pharmaceutical Management.

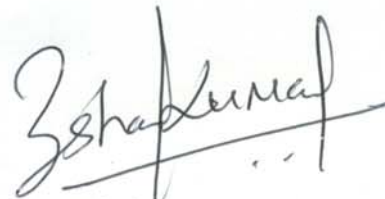
I wish her success in all her future endeavors.



Col. (Dr.) Ashok Kaushik

Dean (Academic & Student Affair

The IIHMR University, Jaipur



Dr. Ashok Peepliwal

Associate Professor

The IIHMR University



BHARAT SERUMS AND VACCINES LIMITED

(CIN: U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India

Tel. : +91-22-6656 0900 / 6656 0980

Fax : +91-22-6656 0933

E-mail : corporate@bharatserums.com

Website : www.bharatserums.com

Date: 11th August, 2017

To whomsoever it may concern

This is to certify that **Ms. Garima Kumari**, First Year MBA – Pharmaceutical Management student from **Institute of Health Management Research, Jaipur, Rajasthan**. Has successfully completed her summer internship program in this organization from **04th April, 2017 to 03rd June, 2017**. The topic of her summer internship was "A Study on naturopathy in gynecology segment".

During the duration of the internship, she has worked under our supervision and guidance and has shown a great amount of sincerity, interest and dedication in carrying out the responsibilities assigned to her.

We are satisfied with the output of her work and we wish her all the success in future.

For Bharat Serums and Vaccines Limited


Akhilesh Mishra

Sr. Vice President – Human Resources.

Corporate Office

3rd Floor, Liberty Tower,
Plot No. K-10,
Behind Reliable Plaza,
Kalwa Industrial Estate,
Airoli, Navi Mumbai,
Pin - 400 708.
Tel. : +91-22-4504 3456
Fax.: +91-22-4504 3200

R & D Centre

3rd Floor, Liberty Tower,
Plot No. K-10,
Behind Reliable Plaza,
Kalwa Industrial Estate,
Airoli, Navi Mumbai,
Pin - 400 708.
Tel. : +91-22-4504 3000
Fax.: +91-22-4504 3200

Thane Factory

Plot No. A-371/372, Road No. 27,
Wagle Industrial Estate,
Thane (West), Pin - 400 604.
Tel.: +91-22-2582 2181, 2582 1399,
+91-22-679 77696
Fax.: +91-22-2582 3640
E-mail: factory@bharatserums.com

Ambernath Factory

Plot No. K-27, Anand Nagar,
Additional M.I.D.C.,
Ambernath (East), Pin -421.501.
Tel.: 0251-262 1645 / 262 1648 / 262 1083,
656 4623 / 656 7857
Fax.: 0251- 262 1089
E-mail: ambarnath@bharatserums.com

Warehouse

Building No. H-4, Premise No.1
Survey No. 15, Sonale Village
Mumbai - Nasik Highway,
Taluka - Bhiwandi,
Dist - Thane, Pin - 421 302.
Tel.: 0252 - 2663 026 / 27

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First of all, I express my sage sense of gratitude and indebtedness to our President, Dr. Vivek Bhandari IIHMR University .

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I would also like to express my deep sense of gratitude to my faculty mentor Dr. Ashok Peepliwal . I am also thankful to Dr. Sandeep Narula. I am greatly indebted to both of them for providing their valuable guidance at all stages of the study, their advice, constructive suggestions, positive and supportive attitude and continuous encouragement, without which it would not have been possible to complete the project .

To place on record, I owe a debt of gratitude to all my teachers for grooming me and my classmates for the inspiration needed to work with dedication and motivation throughout as an Intern at Bharat Serum and Vaccines Ltd .

I hope that I can build upon the experience and knowledge that I have gained and make a valuable contribution towards the industry in coming future .

Overview

Naturopathic medicine doesn't follow a single road to good health. It combines nature with modern science. This approach to health care embraces a wide array of noninvasive techniques and therapies, including traditional healing methods, principles and practices .

Naturopathic medicine focuses on holistic prevention and comprehensive diagnosis and treatment. Naturopathic physicians work with the body's inherent ability to restore and maintain optimal health. The naturopathic physician tries to encourage good health by helping to create a healing internal and external environment .

The History of Naturopathy

Many practices associated with naturopathy date back centuries, but modern naturopathy was founded and named by German physician Benedict Lust in the early 20th century. It was popular in the United States in the 1920s and 1930s. Within a few decades, conventional medicine, also known as "drug therapy" medicine, came into prominence and naturopathy faded. Naturopathy regained some popularity in the 1970s as Americans developed a new appreciation of alternative and "holistic" approaches to medicine .

The Principles of Naturopathy

While various naturopathic organizations have differing perspectives on the scope of the naturopath's practice and different practitioners take different approaches to diagnosis and treatment, traditional naturopaths adhere to certain basic principles :

- **The healing power of nature.** Naturopathy contends that the body has the inherent ability to heal itself and, when working at an optimal level, to ward off disease. Naturopathy is intended to help your body do just that .
- **Treat the whole person.** Naturopaths work from the perspective that health and disease are more than just germs and infection. Mental, physical, spiritual and environmental factors each play a role. Naturopaths take all of these factors into consideration when developing treatment. So, where a conventional health care professional may prescribe medication to suppress symptoms, a naturopath may look for alternative approaches because the goal is to restore health, not simply banish illness .
- **First, do no harm.** This tenet is, of course, part of the Hippocratic Oath taken by physicians. Traditionally, naturopathy focuses on gentle, noninvasive therapies that enhance the healing process. It is this principle that underlies the reluctance to turn immediately to drugs for a cure. Naturopaths generally avoid methods that merely relieve symptoms without addressing the cause. This is the foundation of another principle .
- **Identify the cause.** Instead of treating symptoms, naturopaths seek to identify and treat the underlying cause. Symptoms are not the cause of illness—they simply indicate that your body is out of balance. The cause is often more difficult to identify. It could be anything from a vitamin or mineral deficiency to an emotional problem. By identifying

and addressing (or removing) the cause, the symptoms can be relieved rather than suppressed .

- **Prevention.** Naturopaths place great emphasis on preventive care. Naturopaths assess our risk factors and make suggestions that will support our good health .
- **The physician as teacher.** Naturopaths see themselves as teachers and try to teach patients how to take responsibility for their own health. This may involve suggesting nutritional, emotional, dietary or other lifestyle changes .

Is Naturopathy Effective ?

Naturopaths are willing to work cooperatively with their conventional-medicine counterparts. You should continue your existing treatments while seeking care from a naturopath. Be sure to keep all of your health care professionals apprised of all treatments you are receiving .

Company Profile

Bharat Serums and Vaccines Limited (BSV) is one of the fastest growing biopharmaceuticals companies in India and have been ranked amongst the top Indian Biopharmaceutical companies. With its inception in 1971 by Mr. Vinod Daftary and Bharat Daftary, the company has 2 manufacturing units in Ambarnath, Maharashtra, 3 independent R&D facilities and a horse farm in outskirts of Maharashtra and over 900 employees.

With its 75% of business coming from domestic markets, its international business is slated to grow exponentially.

Vision

To Be an Innovative, Caring and Trustworthy Partner in Bringing Life To Life

- ☐ Mitigating the anguish and suffering of millions .
- ☐ Underlying fairness and transparency in dealings with all stakeholders including employees and business partners .
- ☐ The Group is driven by an informal culture fostering cohesion and innovation

Presence

Domestic

Products are sold through 6 specialized divisions and have over 25 brands.

- ☐ **DIVA**: prime division of BSV, operating in Gynecology and Obstetrics segment
 - o Flagship Brand: Rhoclone and Hucog
- ☐ **ASPIRE**: A complete solution in AST (Assisted reproductive Technology)
 - o Flagship Brand: Foligraf
- ☐ **ELITE**: A tender division of BSV, operating in hospital-based emergency medicine and casualty
 - o Flagship Brand: Tetglob, Equirab, and ASVS
- ☐ **ALTIUS**: Second largest division of the company and operating in Critical Care segment
 - o Flagship Brand: Gamma IV and Albumin
- ☐ **ANAGEN**: Offering cornerstone therapies in Transplantation and Aplastic Anemia
 - o Flagship Brand: Thymogam and Ampholip
- ☐ **UROCARE**: Offering cornerstone therapies in Urological problems
 - o Flagship Brand: Luprodex

International

□□ With a zest born out of the desire to improve health and quality of life globally, BSV started its international business operations in early 2000. The international business operation got a major boost with the commissioning of the new Ambernath plant in 2003 .

□□ The Company's products are registered in more than 45 countries and its manufacturing facilities are accredited and certified by various regulatory authorities from Asia, Latin America, Middle East, Africa , etc

□□ The company also has global subsidiaries namely

- o BSV BIOSCIENCES, INC (United States)

- o BSV BIOSCIENCE, GMPH (Germany)

INTRODUCTION

Summary

The topic assigned was “**A Study on naturopathy in gynecology segment**”

This study was done in different part firstly we interacted with doctors who are specialized in gynecology segment and ask them to fill our questionnaire which consist of all the important questions which was design to know the market knowledge about naturopathy and will this segment will be benefited according to our customers which are doctors.

Methodology

Sample Design:

Descriptive study

Sampling:

Non-probability convenience sampling

Sample population:

Gynecologist in various govt. and private hosp

Sample Size:

Respondents: 100

Hospitals: 29

Sample area:

Jaipur

Tool:

Questionnaire to collect primary data

Microsoft Excel for analysis

Data Collection:

Primary- Through questionnaire and meeting with respondents

Study duration: 40 DAYS

Findings and Interpretation

OBJECTIVE 1 : To study average number of patient treated by doctors in an average of one day.

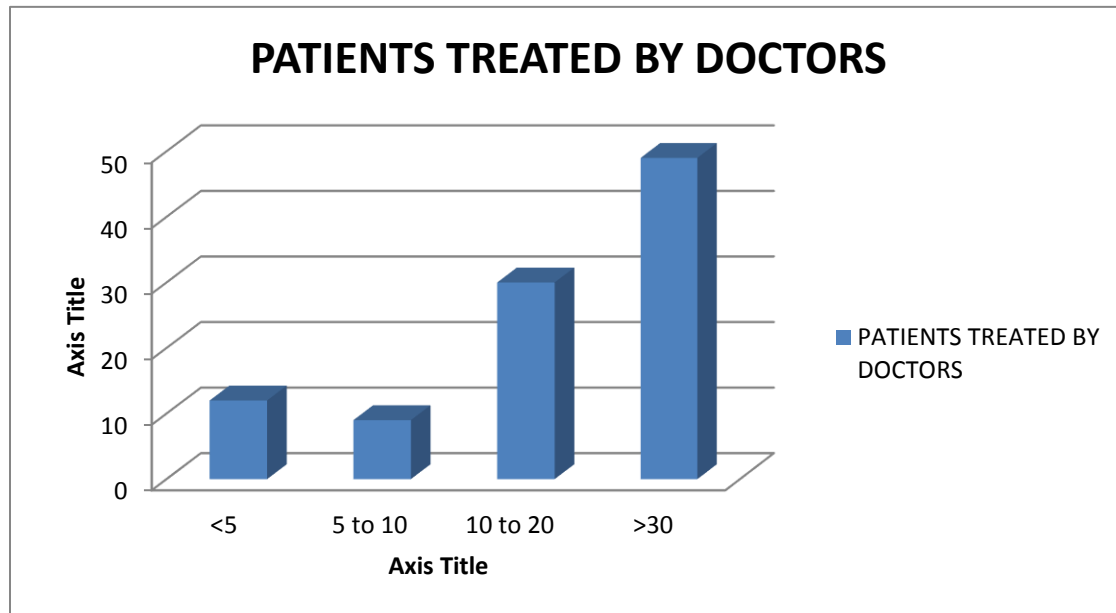


Fig: Denote how much patient's doctor's checkup in each day

Doctors were asked that how many patients are treated every day by them resulted as more than 30 patients which means there is lot of demand in gynecology segment because different kinds of patients are consulting doctors every day for their checkups.

If there are so many patients we have a great opportunity further for many products.

OBJECTIVE 2 To study what are main problems and disorders from which patients are suffering.

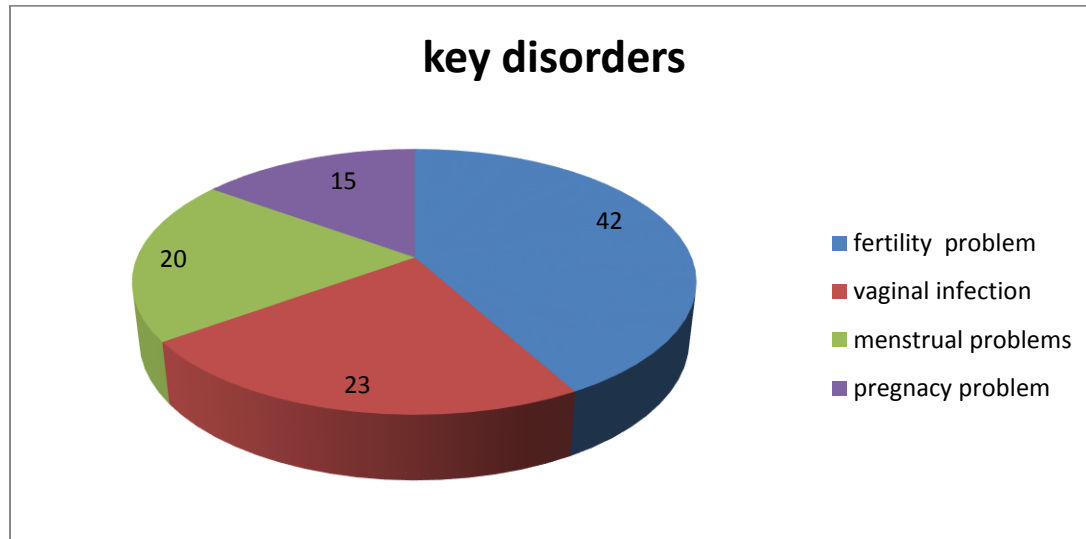


Fig Denoting types of problems in gynecology segment

We asked doctors about problems which patients face mostly in gynecology or what are the most common problem which doctors go through during examinations of patients.

Results which came are as follows: -

Fertility problems are one of the most common and high percentage of people are suffering from this issue we conclude it to be 42 %

2nd important problem was vaginal infection and concluded to be 23 %

3rd most important problem was menstrual problem which concluded to be 20 %

4th problem was pregenancy problem which was 15 %.

Objective 3 To study what is preferred modality of treatment for these disorders

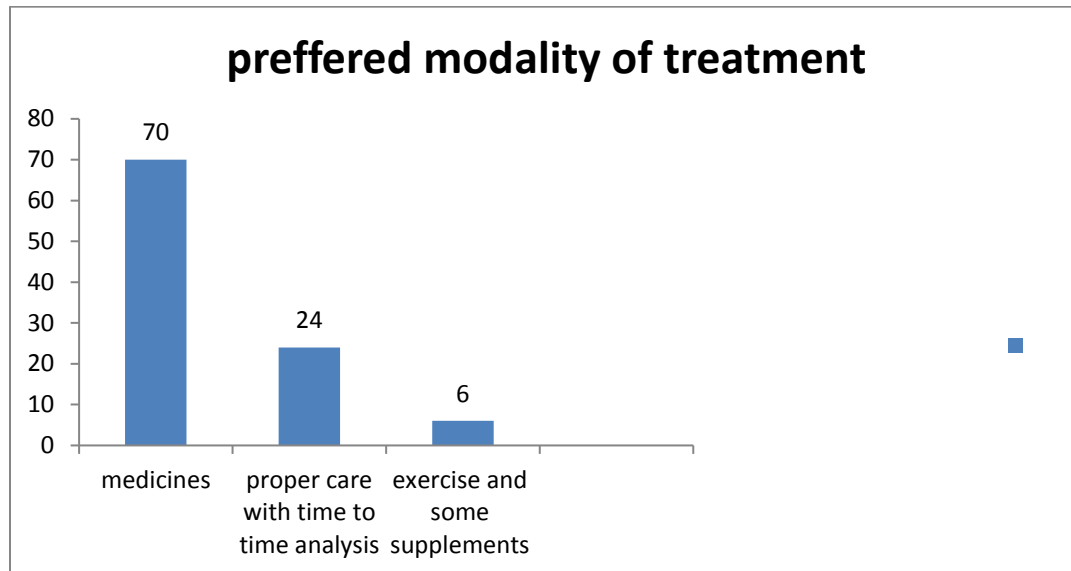


Fig Preferred modality of treatment

We asked doctors about what they prefer for treatment because this can give us idea what mostly doctors are using and how can we generate the demand for naturopathic segment.

Mostly doctors are using medicines which was obvious 2nd most preferred was proper care without any medicines mostly allowing with some habits and proper hygiene.

3rd most important was use of some supplements and exercise.

These data help us to understand what will be the market demand and how can we enter market with naturopathy.

OBJECTIVE 4: Study of awareness and uses of naturopathy products by doctors.

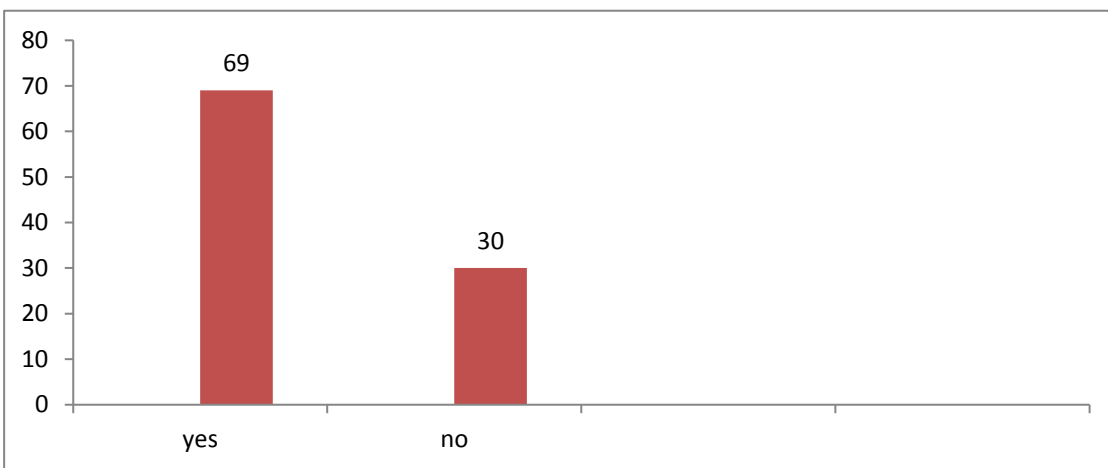


Fig Showing the knowledge of doctors regarding naturopathy

We asked doctors about naturopathy and the answers which we get was approx 69 doctors know about it whereas 30 of them don't know.

If any doctor have idea about naturopathic segment then it became easy for further queries and demand.

OBJECTIVE 5 To Study naturopathy products doctors utilize in their day to day practice?

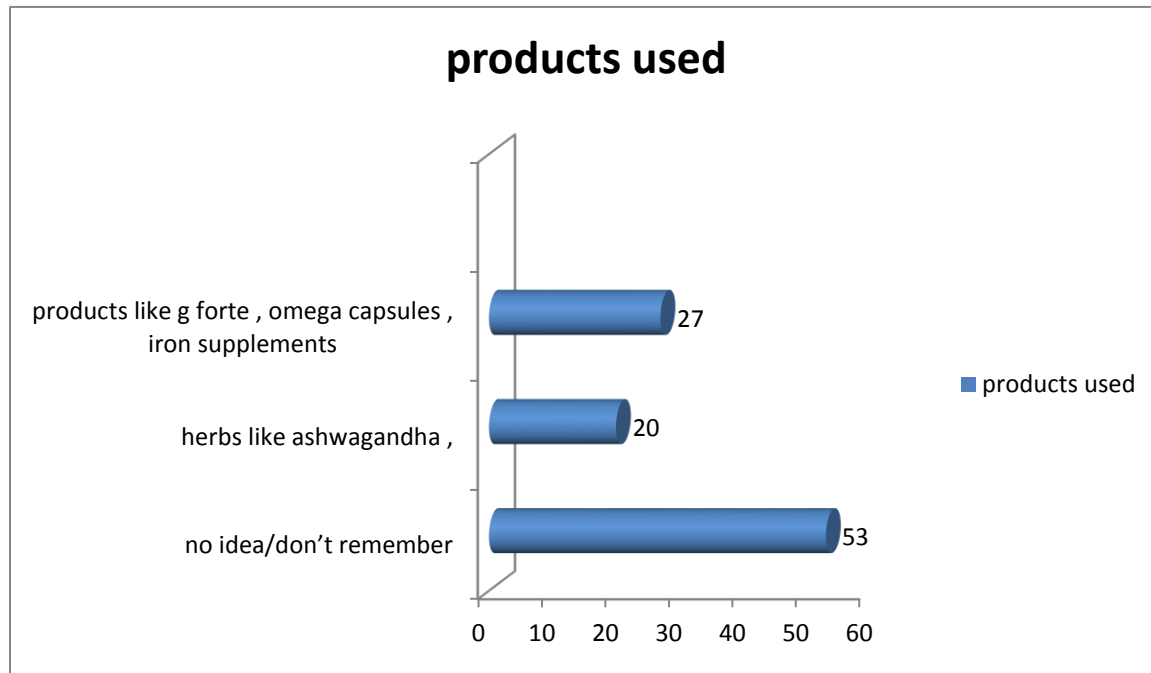


Fig Types of naturopathy products doctors utilize in your day to day practice

Types of products which are used by doctors were some iron supplements, herbs like ashwagandha whereas 53 of them said that they don't have any idea about it.

These data will help us to know market as 53 % of them don't know anything about it we can aware them with different marketing strategy.

Objective 6

To study what are the reasons for usage of naturopathy products?

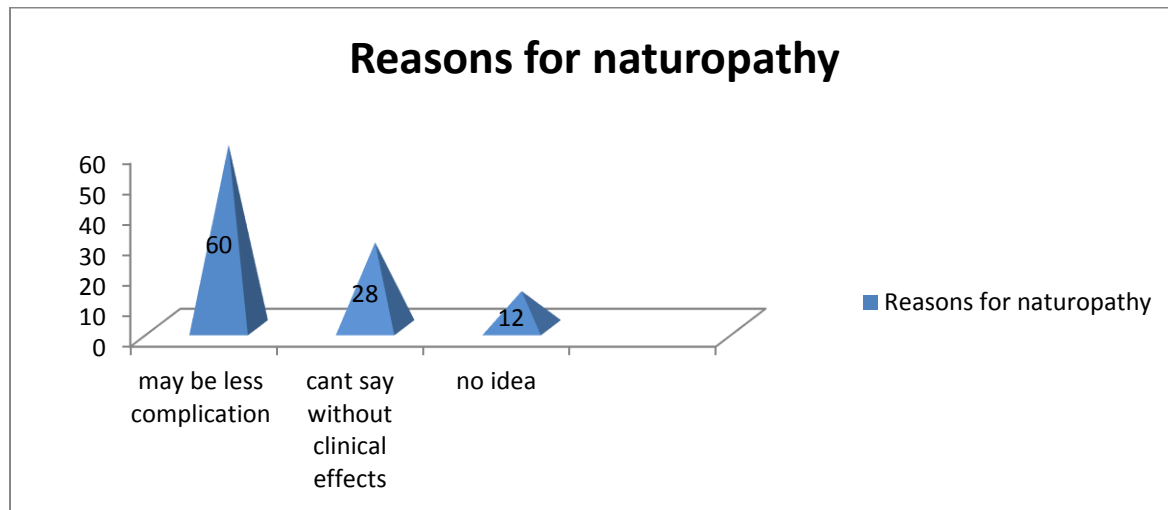


Fig Reasons for naturopathy

We tried to find out the reasons for naturopathy uses by doctors, 60 % of them said they use naturopathy may be use to less complication, doctors were not sure about the use and their effects

While 28% of them said they can't say without any clinical effects whereas 12 % of them said that they don't have any idea about it.

This information may help further for bringing more awareness in this section his and bring products of this regimen.

Objective 7 To Study treatment regimen with these products in gynecology.

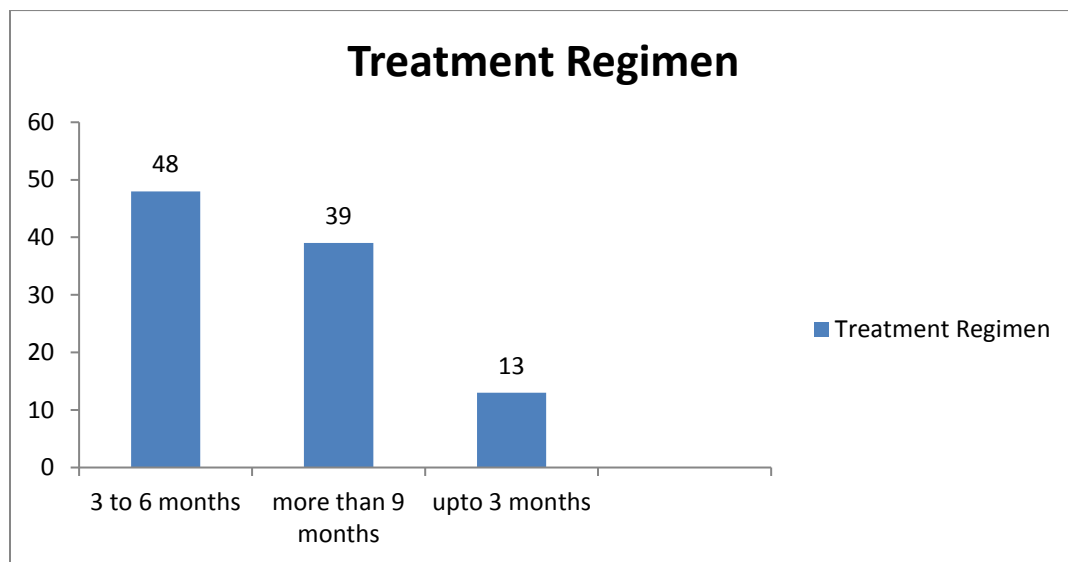


FIG Treatment Regimen

Treatment regimen was asked by doctors mostly the answer which came out as result was 3 to 6 months mostly and second most common answer was more than 9 months which means that approximately doctors think if they use naturopathic product then medication will be for longer duration it may cause more time to treat .

Company can bring those product with high content of API and efficacy can be increased this will enhance the demand and further it would be beneficial for both company and patients.

We can work on the time period value of these medications and which can bring a new era in naturopathy segment.

Objective 8 To study cost of treatment in this segment.

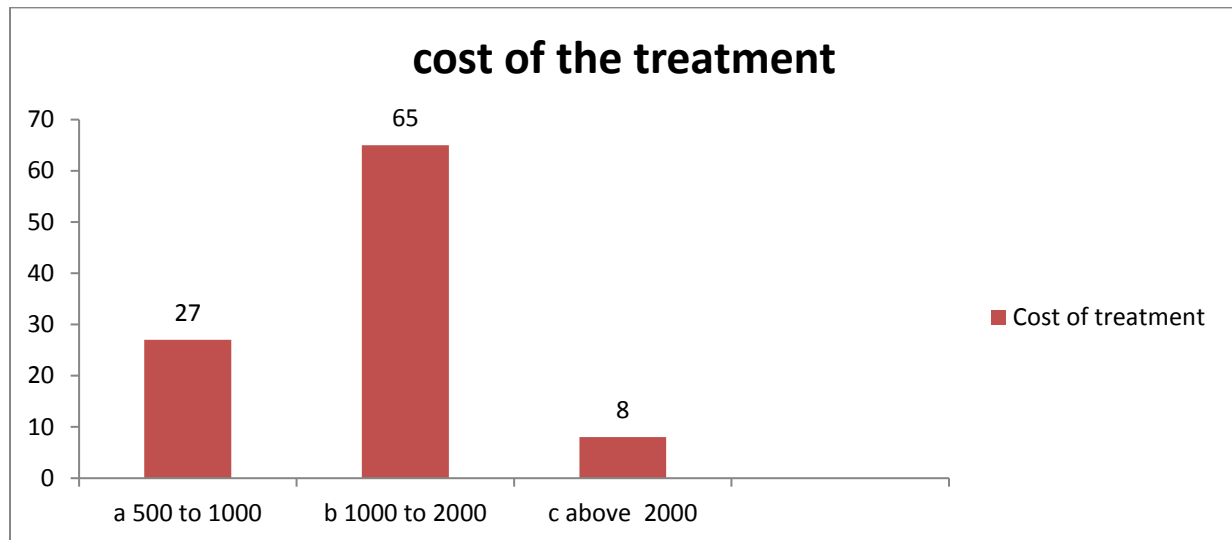


Fig cost of treatment according to doctors

Cost of the treatment mostly recommended by doctors are between 1000 to 2000 doctors mostly 65% of them think it should be between 1000 to 2000.

This help us to understand what should be the cost of the treatment and what should be the price of the product.

Objective 9

TO Study what percentage of patients adhere/complete the treatment regimen?

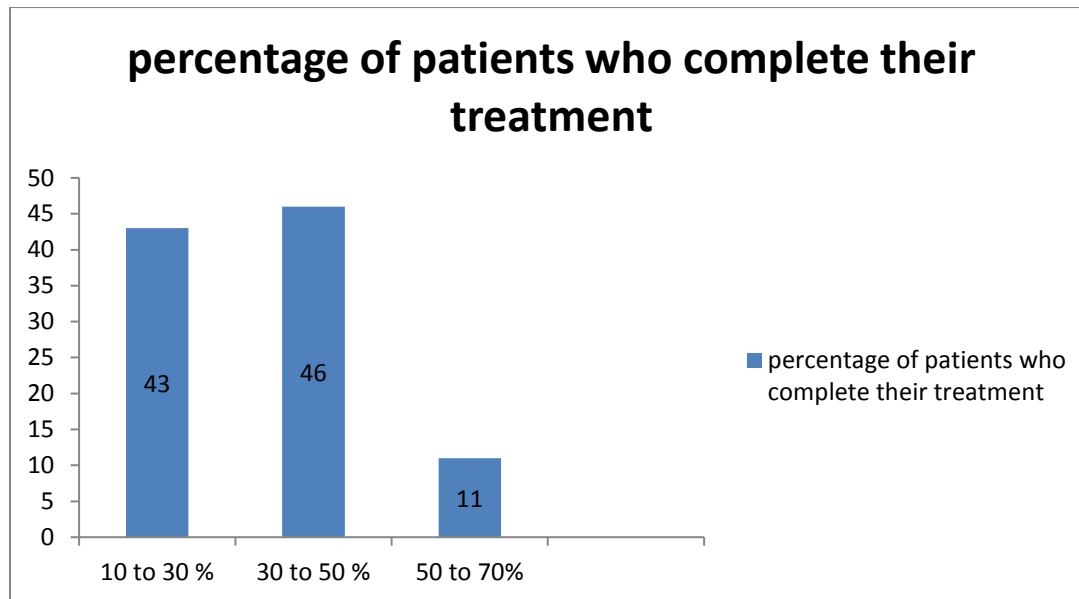


Fig Percentage of patients

30 to 50 percent of the treatment is mostly completed by the patients, here we can think because of more time consuming process or may be due to less awareness people are not completing their treatment which may cause further problems.

Taking medicine regularly is a hectic thing until and unless it is monitored in a proper manner

We can improve efficacy of the medicine and can control these things

Objective 10. We ask doctors to suggest any naturopathic product required to be launched in gynecology if yes which?

Mostly the answer was focused on if these types of products can be used then first preference will be in fertility problems

Second preference was in menstrual problems and then in hormonal issues, Approx 10 percent of them don't have any idea.

OBJECTIVE 11 Study of some suggested supplementary products for fertility which are derived from natural sources

Suggested supplementary products were like some brand g4 ashwagandha herb many of them said that they don't have any Idea regarding this.

Many of them they said that they don't have any idea about it.

Objective 12 Study of experience on patient's improvement in treatment with Natural products?

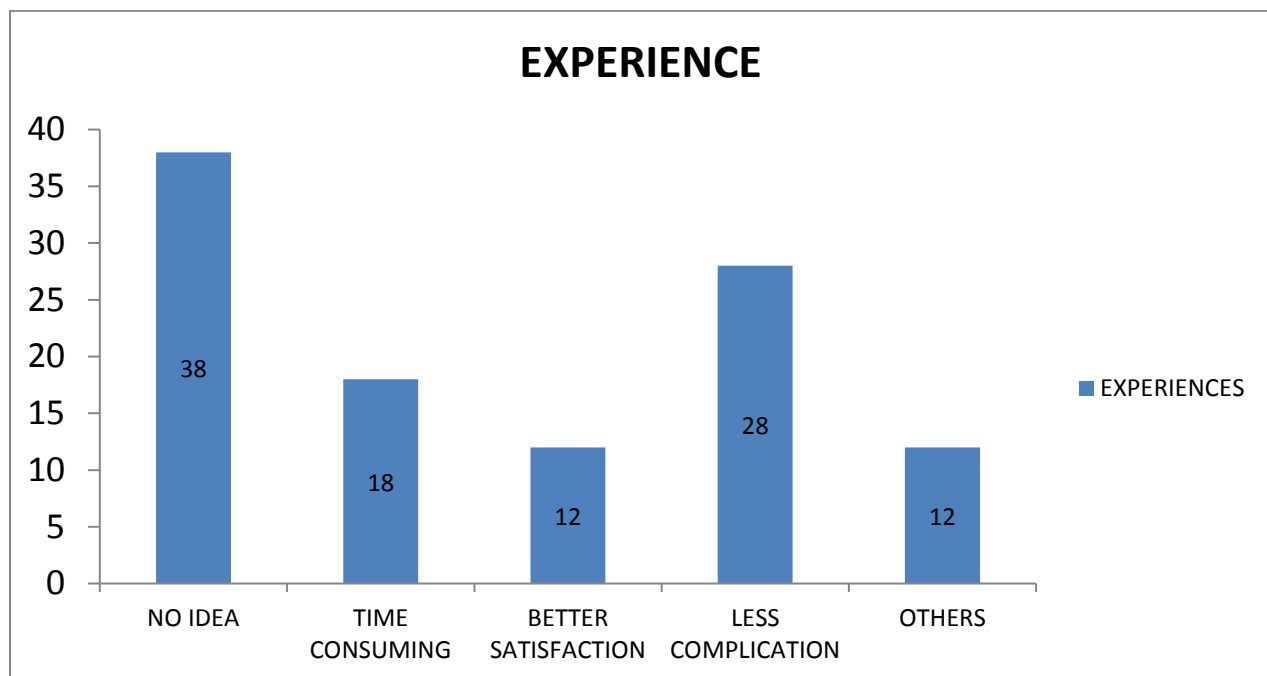


Fig Experiences shared by doctor in reference of effects and consumers perception

Experiences which are shared by doctors are like many of them said that they don't have any idea about it, whereas many doctors even said that there is less complication so they used it or suggested to use.

This helps us to make market strategy of naturopathic segment in a manner that it can be used easily with less complication.

Other Findings

Almost gynecologist is mainly unaware of naturopathy products but if some information which we share it shows that they are really interested and waiting for the products which can heal naturally as there are so many complications.

There is a good chance in a market to explore with this wonderful product which can bring change

Limitations to the study

- ☐ Doctors were not ready to give information easily.
- ☐ Question regarding the brand of preference was not answered by the majority of doctors

Recommendations

1. Market have very less competition in this naturopathic segment mainly marketing strategy should be developed so that doctors can remember that the product is somewhat different from other product and due to less competition and great demand it can be a market builder.

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2. Good opportunity for company.

3. This segment is totally new its need to be understood by doctors and this type of survey should be done even more in different cities.

4. Doctors are coming across many adverse effect and complications which may cause serious problems these type of medication can resolve those issues but marketing strategy should be mainly focusing on its difference.

5. Doctors were like they give naturopathy product just as a supplement but these product should be introduce in market as an core medicine with equal benefits

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ANNEXURE

Questionnaire

1. What is average number of patients you examine with gynaecological problems?
a) <5 b) 5-10 c) 10-20 d) More than 30

2. What are the key disorders/diseases patients complain about?
a) b) c) d)

3. What is your preferred modality of treatment for these disorders?
a) _____ b) c) d)

4. Do you have any usage of products derived from nature?
a) Yes b) No

5. What are naturopathy products you utilize in your day to day practice?
a) b) c) d)

6. What are the reasons for usage of naturopathy products?

7. Do you suggest any naturopathic product required to be launched in gynaecology/ if yes which?
1)_____ 2) _____ 3)_____

8. What are the indication you suggest for the said products?
1)_____ 2) _____ 3)_____

9. Can you suggest some supplementary products for fertility which are derived from natural sources?
1)_____ 2) _____ 3)_____

10. What would be the treatment regimen with these products in gynaecology?
- a) Upto 3 months b) 3-6 months c) 6-9 months d) More than 9 months
11. What is cost of treatment to patients?
- a) Between 500- 1000 /Month b) Between 1000-2000/ Month c) Above 2000 / Month
12. What percentage of patients adhere/complete the treatment regimen?
- a) 10 -30 % b) 30 – 50 % c) 50-70 % d) 70-100 %
13. What is your experience on patient's improvement in treatment with Natural products ?

Probiotics

Probiotic Supplements have been on the rise as more and more adults today start feeling the troubling side effects of poor gut balance. The good news is that ever since the research and development in the cultivation of “good gut bacteria” has evolved, the popularity of probiotic supplements has been rising and rising .

And though we love when new natural alternatives come to market, it often creates a breeding ground for companies who want to prey upon consumers with a true need of improving their digestive health .

Top 5 Signs You Should Be Taking Probiotics

1. Taken **antibiotics, anti-inflammatory (pain meds) or birth control** in the last few years.
2. Experienced **digestive issues, such as constipation, diarrhea, gas, bloating, upset stomach**, or have even had **food poisoning** at some point .
3. Noticing **skin blemishes, acne**, dullness in skin, Rosacea, Psoriasis, or Eczema .
4. Feeling **depressed**, moody, irritable, brain fog or **low energy** .
5. Get **colds or the flu** frequently throughout the year .

“The Importance of a “Balanced Gut”

Our digestive system is a pretty amazing part of our body. The gut breaks down food and liquids into their chemical components (carbohydrates, fats, proteins), which the body uses for energy and cellular regeneration. It also regulates hormones and activates the immune system. Our gut microbiome is made up of trillions of microorganisms (bacteria, fungi, and viruses). When in balance, the good bacteria in your gut keep you healthy by preventing an overgrowth of bad bacteria such as harmful microbes, yeasts, and parasites which can cause an imbalance .

“Good Gut” Bacteria SECRETS You May Not Have Known

1. You have **more nerves in your gut** than you do in your entire spinal cord .
Your **gut has 100 trillion bacteria, 3 pounds worth**, and all those cells are **more** than the human cells that can be found in the rest of your entire body. That’s a lot of cells in your gut
3. Having good gut bacteria dictates how well your **immune system** will function .
4. Want **glowing and clear skin**? Good bacteria plays a vital role in the appearance of your skin .
5. A surprising 95% of the **serotonin**, the happy molecule in your brain, is made in your gut!
Balance your gut with good bacteria and you can help **improve your mood** and achieve more **mental clarity** .

How Probiotic Supplements work ?

Probiotics supplements contain live strains of “good bacteria,” delivered to your gut in a convenient daily pill, which can help to balance your intestinal microbiome. Building your gut with more friendly bacteria can help prevent the over-colonization of “bad bacteria” which is a major factor in how well your immune system can respond to invading harmful pathogens and fight prevent infections .

Research has shown that an optimal balance in your gut is 85% “good” bacteria to 15% “bad” bacteria .

Although the perfect percentage may vary for each individual person, the most important objective to achieve health is to create an environment for healthy bacteria to flourish. **It is essential to choose a high-quality probiotic brand, with the correct strains in the correct proportions, to help bring your gut flora back into balance and prevent the overgrowth of “bad” bacteria .**

Probiotics in Gynecology

Influence on the human health has been clinically proved can be described as probiotics. The other requirements regarding probiotics strains are: safety of administration, lack of toxic metabolic products, possibility of isolation from human organism, resistance to technological processes, meaning the adequate

survival and activity, adherence to intestinal mucosa, antagonistic activity against pathogenic microorganism and the stimulation of immune system .

PROBIOTICS AND PREBIOTICS

Along with probiotics, frequently prebiotics appear – food components that do not influence the digestion process but activate the growth or activity of selected bacterial intestinal strains. They also favourable change the microflora of the host organism, affecting the improvement of health. However, symbiotic means the food product which containing probiotics and prebiotics. Recently the interest of so-called functional food is growing, which means the food products, with harmful components removed or enriched with active physiological substances in order to improve the nutritional values and favourably influence the organism

PROBIOTICS AND THEIR IMPORTANCE FOR HUMAN

The most important types of strains are *Lactobacillus* and bifid bacterium. Recently, the interest of researchers is focused on *Lactobacillus GG*, variant of *L. casei* sp. *rhamnosus*. Primary germ-free gastrointestinal tract of the newborn is in short time colonized by *Escherichia coli*, *Enterococcus*, *Clostridium* and following *Lactobacillus* and *Bifidobacterium* which tend to dominate. The rich source of probiotics for newborn is breast milk. The composition of the physiological flora of the gastrointestinal tract is most intensively formed in first two years of life. It is assumed, that physiological flora components consist of about 500 microorganism strains, mainly anaerobics.

The main tasks of the probiotic flora in gastrointestinal tract are: to preserve against the pathogenic microorganisms colonization, to stimulate regenerative processes of intestinal mucosa, to increase peristalsis, to participate in digestion of some food components, the synthesis of several vitamins, inhibition of the cholesterol absorption, the increase of calcium absorption, the anticarcinogenic properties and the stimulation of immune system. Recently, the growing interest in probiotics is a result of increasing possibilities to administer them both in prophylactics and therapeutics. The probiotics are proved to be effective in the maintenance of normal composition of intestinal flora as well as in prophylaxis and treatment of infectious diseases of gastrointestinal tract (antibiotics therapy, rotaviruses and bacterial diarrheas). Probiotics diminish the intensification of lactose intolerance, normalize the peristalsis in elderly.

PROBIOTICS IN GYNECOLOGY

The basic vaginal biocenosis consists of about 100 bacterial strains, aerobic and anaerobic, mainly *Lactobacillus* which prevents infections. A dynamic balance in the number of separated components of physiological vaginal flora is observed.

The disturbance of this balance leads to development of infections in genitourinary tract. Many factors cause vaginal biocenosis: the menstrual cycle phase, age, pregnancy, hormonal and immunological disturbances, infections, drugs (antibiotics therapy), contraception, improper hygiene, chronic diseases, artificial insemination, diet and sexual activity.

The main purpose of *Lactobacillus* and other bacteria taking part in regular, normal vaginal biocenosis is maintenance of proper pH of the vagina, production of bacteriocins, hydrogen peroxide and lactic acid, to prevent multiplying of pathological flora and stimulation of immunological response in the vagina. Moreover, it was found that they are able to produce biosurfactant and collagen binding proteins which inhibit the adhesion of pathogens to vaginal epithelial cells. The probiotics are capable to adhere to vaginal epithelial cells, and to form the protective layer (biofilm) providing the barrier against pathogens.

The most frequent vaginal infections are bacterial vaginosis (BV), candidiasis, and trichomoniasis. Only two strains of *Lactobacillus rhamnosus GR-1* and *Lactobacillus fermentum RC-14* comply with WHO/FAO requirements relevant to the efficacy of activity, because they were isolated from the environment of the urinary tract, they show the great affinity to vaginal epithelium, have

the capability to colonize the vagina, inhibit the growth of pathogens and reveal the range of the resistance on antibiotics character specific for a given strains .

BACTERIAL VAGINOSIS

Bacterial vaginosis (BV) is a disorder of the balance of vaginal microflora with regard to anaerobic bacteria, which number may increase 100-fold. This is the most frequent cause of abnormal vaginal discharge in women in reproductive age

The genitourinary infections are a very prevalent problem. The incidence of Probiotics in gynaecology infections of urinary bladder and vagina occurs in billion cases a year, which significantly deteriorates the quality of life and moreover, cause additional consequences such as increase of risk of preterm delivery due to chronic bacterial vaginosis .

The most important is the prophylaxis of recurrence of these infections. The use of probiotics shows the importance of the prophylaxis of infections in genitourinary tract of women. Currently, there are numerous drugs administered orally and vaginally. It was shown that most of components of natural vaginal flora originate from gastrointestinal tract and can be transmitted from anus. Hence, regular taking of orally administered drugs containing probiotics can normalize the microflora of the vagina essentially diminishing the number of E coli and Candida albicans

The efficacy of the vaginally administered drugs was confirmed in bacterial vaginosis and in cases of some pathogens causing the infections of urinary tract . It was also observed that daily consumption of yogurts, containing Lactobacillus acidophilus diminish the incidence of Candida albicans Infections in vagina .

The favourable activity of probiotics in the prophylaxis of recurrent infections of urinary tract and bacterial vaginosis was also found in postmenopausal women. In menopausal women the level of estrogens is decreasing, the number of Lactobacillus is diminished, and the pH is increasing, what enhance the multiplying of the Enterobacteriaceae spe -cies, frequent cause of infections of the genitourinary tract. The incidence of these infections diminishes along with growing number of Lactibacilli observed along with use of hormonal replacement therapy .

CONCLUSION

According to newest reports, probiotics are a important tool in the therapeutic procedure and essential component supporting the pharmacological treatment, especially along with rapid increase of antibiotic resistance of the bacteria. The safety and efficacy of application creates more possibilities of their administration. It is essential to know that there are potential side effects of probiotics' effects such as systemic infections, overstimulation of immunological system or genes transfer. Hence, it is a necessity of further investigations in this field .

It is also necessary to label the probiotics products precisely. The market's labels should contain the name of the used strain, the number of viable bacteria and the indications for treatment. Many aspects related to the mechanisms of action probiotics' effects yet to be explained and require further clinical trials in order to prove the principles and safety .

So, with all these we are here with the new product of probiotics which is **Progyn**



Progyn Colony forming units in progyn is approximately 50 billion which proved to be better supplement. It has 17 different strains which give it a unique identity than others. It has substrains which enhance its quality and give a recommendation that its better than others. Note:- As shown in the example below, the substrain will be located to the right of each strain, followed by a trademark symbol: Bifidobacterium lactis BI-04™ Contains nutra flora fiber which is most effective in reculturing our gut. Packed in dark amber colored bottle as they are very sensitive to light. Freeze dry probiotic which is stable without refrigeration.	Probiotics Approximately all probiotics have 30 to 35 billion CFU which is not so effective . Mostly have 5 to 14 strains. Mainly most generic one doesn't claim to have substrain Do not claim to have nutra flora. Not necessary to packed in dark amber colored bottle. Need refrigeration.
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Concerned Things (Market Understanding) .

Probiotics are microorganisms which confer a series of innate health benefits to the host, having a wide range of applications. These are widely used globally due to advancement in the relationship between nutrition and health besides their promising therapeutic benefits and negligible side effects. Indian probiotic industry is achieving its pace at steady rate with opportunities for rapid growth in near future .

Indian probiotic market is valued at \$12 million in 2011, is expected to witness a CAGR of 11 per cent by 2016 .

Introduction of a range of pharmaceutical probiotic formulations in the market further increased the turnover of probiotic industry. The future of probiotic foods is even promising, as modern consumers are worried to maintain their personal health, and expect the food that they eat to be healthy and capable of preventing illness. Overview of the current market situation of probiotics in India, range of products available, key players involved in this business along with some critical comments on existing guidelines for probiotics with recommendations for strict regulations to ensure patient safety and survival of such products as pharmaceuticals. *Probiotics in India: Current status and future prospects (PDF Download Available)*. [https://www.researchgate. \(e-tal\)\]](https://www.researchgate. (e-tal)]).)

However, the demand of probiotic food alone in global market was 27.9 billion USD in 2011 and is expected to increase at a 6.8% CAGR in 2016 (Raghuwanshi et al. 2015). In India, the value of probiotic market was 12 million USD which will grow at a CAGR of 11% by 2016 (Sharma et al. 2013). The data clearly indicates that the graph of probiotic business will flourish very rapidly in upcoming years .

Future perspectives

Although there are many probiotic products currently available to consumers, both as functional food and nutraceuticals; there is still uncertainty surrounding the structure of regulation of these products. As the area is growing and establishing, changes to existing regulatory process may be required to cater the needs and safety of patients and users globally. Further oriented research is required to answer the key questions involving the actual mode of action; optimal dosage and duration of probiotic therapy; origin and source of probiotic strain; strain specificity and stability of health claim

Safety for probiotics : -

Lactic acid bacterial strains isolated from either of the above discussed sources are generally recognized as safe (GRAS) and are being extensively exploited for their health benefits (Cross et al. 2002; Puertollano et al. 2008). As per FAO/WHO (2001), multiple reports support safety and efficacy of specific strains of probiotics, but these benefits cannot be extrapolated to other strains without experimentation. A full inventory of the risks is to be determined in different populations, at different doses and using different delivery modes and matrices (Papadimitriou et al. 2015). Strains to be used as probiotic should be screened for safety parameters including antibiotic susceptibility, presence of antibiotic resistance genes, haemolytic activity, hydrogen peroxide production, biogenic amine production, mucin degradation etc

Probiotics in health and disease management

Diarrhea

Imbalance between beneficial and harmful bacteria of intestine results into diarrhea. The factors behind, determine the type of diarrheal infection i.e. antibiotic associated diarrhea, pediatric diarrhea, travellers' diarrhea etc. In all cases, overgrowth of harmful pathogen causes severe watery bowel movements and abdominal cramps. Supplements of probiotics are very effective in restoration of the natural ratio between good and bad intestinal residents (Reid et al. 2011). Probiotics are also efficient in calming down the inflammation in intestinal epithelium through maintaining immunological homeostasis of the host

(Fong et al. 2015).

Lactose Intolerance

A significant per cent of world adult population is unable to produce lactase enzyme which makes them intolerant to lactose containing dairy products (Swagerty et al. 2002). Reduced ability to digest dairy products also increases the risk of deficiency of calcium and several other accompanying nutrients in people with lactose intolerance. Probiotic lactobacilli in fermented dairy products are capable to reduce the intolerance symptoms by delivering the significant amount of bacterial lactase to the host stomach and intestine. Several studies have revealed that probiotics could effectively decrease the lactose mediated discomfort and improve the nutritive value of the diet in target population

Inflammatory bowel disease (IBD)

Inflammatory bowel disease (IBD) is the chronic and relapsing intestinal disorder comprising of two distinct stages: Ulcerative colitis (UC) and Crohn's disease (CD). Inflammation in UC is restricted to the rectum and colon, while CD inflammation can occur throughout the gastrointestinal tract. The degree of inflammation also differs in both conditions. In UC, microscopic lesions are limited to mucosal layer whereas more severe conditions observed in CD, wherein damages are widespread to the thickness of intestinal epithelium. The cause of IBD is associated with an unusual response for luminal antigens in a genetically susceptible host .

Metabolic disorders – Diabetes, Obesity and Cardiovascular diseases

Metabolic disorders represent a cluster of commonly recognized life style disorders. Three major metabolic disorders diabetes, obesity and cardio vascular diseases are being recognized as utmost risk factors for human health and life. Genetic and sedentary life style are among the main causes of development of metabolic malfunctioning which are further supported by increased stress and bad eating habits. The visible global burden of metabolic syndrome is now significantly affecting the quality and span of human life. In 2013, a report by Murray and Lopez on global burden of disease demonstrated that metabolic syndromes are among the top 10 death causing diseases in US. According to International Diabetes Federation (IDF) the annual direct health care cost of only diabetes is approximately 286 billion dollars which will increase to 395 billion dollars by 2025 .

Allergy

The prevalence of allergic diseases like eczema, asthma and food allergy have significantly increased in developed world. This phenomenon is explained by hygienic hypothesis; which suggests that the reduced exposure to microbial antigens in early life establish a shift in immune system toward Th2 type of response. The shifting toward Th2 causes a reduced Th1/Th2 ratio of immunological machinery and develops an allergic type mucosal immunity .

Additional health benefits

The mechanism of action of probiotic is conferred by its interaction with host as well as the resident microflora dwelling within us or on our mucosal and skin surface. Thereby, the beneficial effect of probiotics completely depends upon the genetic and microbiological structure of the human body. The discrete beneficial functional effects of probiotics have been described in humans with specific immunological conditions such as pregnant women (Lindsay et al. 2013), Elderly (Eloe-Fadrosh et al. 2015), Infants (Bin-Nun et al. 2005), and athletes (Nichols 2007; Pyne et al. 2015)

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