

Evaluating the Role of Dienogest in Treatment of Endometriosis and Prepare Brand Launch Plan

By

Akanksha Sharma

*Dissertation submitted for the partial fulfillment of the
MBA Pharmaceutical Management*

Academic year, 2015-2017



The IIHMR University, Jaipur

1, Prabhu Dayal Marg, Sanganer, Airport
Jaipur 302029, Rajasthan
Ph: 0141 3924700, Fax: 3924738
Website: www.iihmr.edu.in

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Ph: 0141 3924700, Fax: 3924738
Website: www.iihmr.edu.in

TO WHOMSOEVER MAY CONCERN

This is to certify that **Akanksha Sharma** student of **MBA Pharmaceutical Management** from The IIHMR University, Jaipur has undergone internship training at **Delcure Lifescience Ltd Mumbai** from **February 6th, 2017 to May 5th, 2017**.

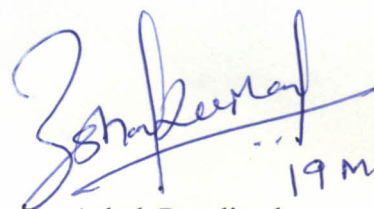
The Candidate has successfully carried out the study designated to her during internship training and her approach to the study has been sincere, scientific, and analytical.

The Internship is in fulfillment of the course requirements.

I wish her all success in all her future endeavors.



Dr. Ashok Kaushik
Dean - Academics and Student Affairs
The IIHMR University, Jaipur



Dr. Ashok Peepliwal
Associate Professor

19 May 2017

The IIHMR University, Jaipur



CIN : U24100DL2013PLC286876
Corporate Office : Kerom-3rd Floor
Plot No. A-112, Road No. 22, Wagle
Industrial Estate, Thane (West) 400 604
Tel : 022 2581 6700
Fax : 022 2582 6722
Email : corporate@delcure.co.in
Website : www.delcure.com

To Whom So Ever It May Concern

The certificate is awarded to **Ms Akanksha Sharma** student of The IIHMR University, Jaipur. In recognition of having successfully completed her dissertation project in the department of **Marketing** from month of Feb 17 to May 2017 under the guidance of **Mr Vineet Razdan-** Sr. GM Sales & Marketing, DelCure LifeScience Ltd, Mumbai.

She comes across as a committed, sincere & diligent person who has a strong drive and zeal for learning.

We wish him/her all the best for future endeavours.

DelCure LifeSciences Limited

A handwritten signature in black ink, appearing to read "Shirish Vankudre".

Shirish Vankudre
General Manager -HR

Regd. Office : 303, 3rd Floor, Plot No. 2, Vardhaman Plaza, Saraswati Vihar, Delhi-110034



THE IIHMR UNIVERSITY, JAIPUR

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **"EVALUATING THE ROLE OF DIENOGEST IN TREATMENT OF ENDOMETRIOSIS AND PREPARE BRAND LAUNCH PLAN"** and submitted by **Akanksha Sharma** Enrollment No. **IIHMR-U/01/2015-17/0031** under the supervision of **Dr. Ashok Peepliwal** for award of MBA in **Pharmaceutical Management** of the University carried out during the period from **6th feb to 5th May 2017** embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.

A handwritten signature in blue ink, appearing to read 'Akanksha Sharma', with a stylized flourish at the end.

Signature

THE IIHMR UNIVERSITY, JAIPUR

CERTIFICATE BY SCHOLAR

This is to certify that all ethical issues have been considered while collecting data for my dissertation titled **"EVALUATING THE ROLE OF DIENOGEST IN TREATMENT OF ENDOMETRIOSIS AND PREPARE BRAND LAUNCH PLAN"**



Signature of student

Akanksha Sharma
MBA- Pharmaceutical Management
Roll.No. - 0031

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For the successful completion of my work, I am thankful to **Dr. Samaresh Debnath (Marketing Manager)** for his guidance and support. Without his encouragement, guidance and interest, this project would not have been materialized.

I would also like to show my gratitude towards Distribution and MIS Department and the entire team of Winspire division for providing the best of working environment and ambience.

I would also like to sincerely thank all the employees of Delcure Lifesciences Limited, Mumbai and IIHMR, Jaipur who either directly or indirectly contributed towards completion of the project and for their patient co-operation.

I hope that I can use this experience and knowledge that I have improved in this dissertation and make a superior involvement to the industry in the approaching future.

EXECUTIVE SUMMARY-

The study aimed to analyse the role of Dienogest and market positioning of Dinotop(Dienogest) among the Gynaecologists in two cities.

Semi-structured questionnaire was utilized for data collection from respondent i.e. 30 doctors comprising of Gynaecologist, from Mumbai and Nagpur. Data was analysed by compiling it & findings provided with doctor's opinion and a comprehensive review of the market situation to be used for framing and suggesting the market positioning strategy.

The project was carried out in 3 stages:

The first stage was to study about the Endometriosis, Dienogest which is used for its treatment, Market competitors and prepare a questionnaire followed by stage two which involves meeting with the gynaecologist in various hospitals and clinics in Mumbai and Nagpur region and conduct the survey. After the completion of the survey, the last stage followed which includes analysing the data and getting a conclusion.

Following findings were observed after meeting with Gynaecologist, in two cities:

- Majority of gynaecologist examine lesser number of endometriosis patients therefore the population of the disease is less in number, 60% of Gynaecologists examine 5-10 number of patients.
- Majority of gynaecologist are going over maximum diagnose of 45-55 age group patients.
- 60% of gynaecologist preferred pain medication as a first choice of therapy
- 35% of gynaecologist preferred estrogen & progestin combination.
- Majority of gynaecologist i.e. 35% are giving preference to pelvic exam, because it clearly diagnose endometriosis associated with pelvic pain
- 50% of gynaecologist are giving NSAIDs for the pelvic pain associated with endometriosis
- It was concluded that majority of endometriosis patients i.e. 48% are treated by Dinofirst(Akumentis).
- Majority of gynaecologist i.e. 40% preferred patient compliance while 25% looks forward towards detailing and 20% referred leaf behind literature which includes the medical literature about product.
- Major challenges in both the regions which Gynaecologist face in the current treatment options are as follows:

- ✓ Prohibitive cost of the therapy
- ✓ Patient compliance
- ✓ Relapse rate
- Following sign and symptoms noticed in endometriosis patients-
 - ✓ Infertility
 - ✓ Dyspareunia
 - ✓ Dysuria
 - ✓ Dysmenorrhea
- Majority shows that 75% gynaecologist were satisfied with visual aid communication

❖ Positioning of new launch brand-

Pay-off line- Enjoy top quality of life.

Target- High profile gynae.

Segmentation- Pelvic pain associated with endometriosis

Promotional inputs-

- ✓ Distributing FAQ related with Endometriosis.
- ✓ Distributing Clinical trials data based on effectiveness of Dienogest over endometriosis.
- ✓ Arranging conferences and seminars attended by Key opinion leaders in this field.
- ✓ Distributing LBL over different clinics and get the response by customers.
- ✓ Distributed medical booklet for product information

❖ Market & Prescription trend-

- ✓ Total market of Dienogest till FY'16-17 was 13.44 cr.
- ✓ From prescription trend it was found the Dinofirst brand is leading in the market of Akumentis .

BACKGROUND

Gynaecology Segment

Gynaecology is a branch of medicine that attentions in the treatment of females, precisely in the treatment of illnesses and difficulties supplementary with reproductive organs. A doctor who organizes this branch of healthcare is detected as gynaecologist. Obstetrics stands for a branch of medicine that deals with the overhaul of women in pregnancy and delivery. A physician who does obstetrics is termed obstrecian. Doctor succeed in both areas is called OBGYN.

Gynaecological Disorders

Menstrual Disorders:

- Heavy menstrual haemorrhage
- Menstrual pain and misdeed
- Pre-menstrual condition (PMC)

Family Planning:

- Contraception – temporary and permanent
- Mirena insertion
- Implanon insertion
- Assure sterilisation
- Fertility Management segment

Pap smear abnormalities:

- Routine pap smears and maintenance of abnormal smears.
- Colposcopy
- HPV immunization

General Gynaecological problems:

- Ovarian nodules
- Pelvic discomfort

- Endometriosis
- Polycystic ovarian syndrome (PCOS)

Menopause:

- Characteristic treatment including hormone replacement therapy
- Osteoporosis reserve, screening and treatment
- Post-menopausal flow

Pelvic floor disorders:

- Pelvic structure prolapse
- Urinary incontinence
- Recurrent urinary tract infection

Infertility:

- Exhaustive infertility valuation
- Complete infertility surveys
- Assisted conception and ovulation keeping fit

Other:

- Calculation and analysis of gynaecological cancers
- Dealing of pre-cancerous gynaecological cuts

INTRODUCTION

The female reproductive system is consisting of the internal and external sex organs which function in human reproduction system. The female reproductive system is juvenile at birth and develops to maturity at adolescence to stand able to produce gametes, and which to carry a foetus to full term. The internal sex organs are uterus and Fallopian tubes, and berries . The uterus or womb accommodates to embryo that grows hooked on the foetus . The uterus produces vaginal and uterine secretions that support the transfer of sperm to Fallopian tubes . The ovaries produce ova. The exterior sex organs are also named as the genitals and these are the organs of the vulva as well as labia , clitoris and vaginal opening . The vagina is linked to the uterus at the cervix .

MENSTRUAL CYCLE

The menstrual cycle ruled by hormonal fluctuations . These changes could be altered by using hormonal birth control to avert pregnancy. Individually cycle can be at odds into 3 phases based on events in ovary or in uterus. The menstrual cycle is methodical natural change which occurs in the female reproductive system that kinds pregnancy probable . The cycle is essential to yield ovocytes, and for preparation of the uterus for pregnancy Up to 80% of female's description have symptoms during the 1-2 weeks prior to menstruation. Common symptoms include acne, fond breasts , bloating, feeling tired, irritability and mood changes . These symptoms delay with normal life and therefore qualify as premenstrual syndrome in 20 to 30% of women .

ENDOMETRIOSIS

Endometriosis can cause pain sometimes severe especially during period. Fertility problems also might develop. Fortunately, effective treatments are available. Endometriosis is defined as painful disease which tissue normally lines inside the uterus & endometrium grows outside uterus . Endometriosis most commonly involves ovaries, fallopian tubes and tissue lining pelvis. Rarely, endometrial tissue might spread outside pelvic organs.

SYMPTOMS

Common signs and symptoms of endometriosis may include:

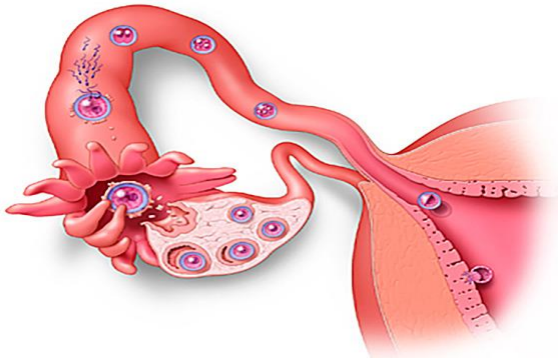
- 'Painful periods (dysmenorrhea). Pelvic pain and cramping may begin before your period and extend several days into period. It may also have lower back and abdominal pain .
- 'Pain with intercourse, Pain during or after sex is common with endometriosis .
- 'Excessive bleeding. It may experience occasional heavy periods (menorrhagia), bleeding between periods (menometrorrhagia)
- 'Infertility. Endomet"riosis is first diagnosed in some women who are seeking treatment for infertility .

CAUSES

Although the particular cause of endometriosis is not confident, possible explanations include :

- Retrograde menstruation. Menstrual blood consist of endometrial cells flow back through fallopian tubes into pelvic cavity instead of ready of the body. These displaced endometrial cells stick to the pelvic walls & surfaces of pelvic organs, where they grow and continue to solidify and bleed over the course of each menstrual cycle.
- Transformation of peritoneal cells In recognized as the "induction theory," experts propose that hormones or immune factors promote transformation of peritoneal cells, that line the inner side of your abdomen into endometrial cells .
- Surgical scar embedding. After a surgery, such as a hysterectomy or C-section, endometrial cells may attach to a surgical opening .
- Endometrial cells transport. The blood vessels or tissue fluid (lymphatic) system may transport endometrial cells to other parts of the body.
- Immune system disorder. It is possible that a problem with the immune system might make the body unable to recognize & destroy endometrial tissue that is growing outside the uterus.

COMPLICATIONS



Fertilization and implantation

- Infertility

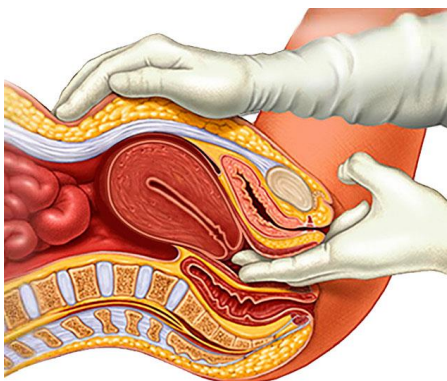
The main complication of endometriosis is impaired fertility. Approximately 1/3 to 1/2 of women with endometriosis have difficulty receiving pregnant.

- Ovarian cancer

Ovarian cancer does happen at higher than expected rates in women with endometriosis. But the complete lifetime risk of ovarian cancer is low to begin with .

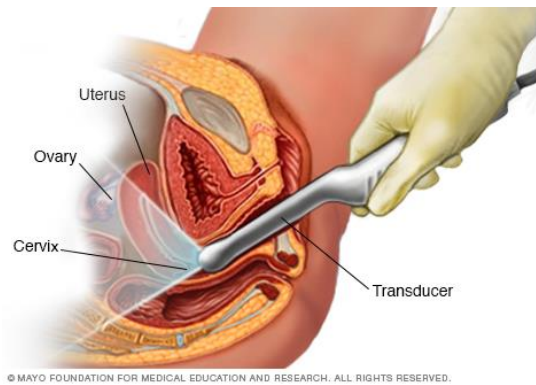
DIAGNOSIS

Pelvic exam



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Transvaginal ultrasound



TREATMENT

Treatment for endometriosis is regularly with medications or surgery. The approach you and your doctor indicate will depend on the severity of your signs and symptoms and whether you hope to convert in pregnant.

Generally, medical recommends annoying conservative treatment approaches first, opting for surgery as a last resort.

Pain medications

An OTC pain reliever, such as (NSAIDs) ibuprofen (Advil, Motrin IB, others) or naproxen (Aleve, others), to help ease painful menstrual cramps.

Hormone therapy

Supplemental hormones are occasionally effective in reducing or eliminating the pain of endometriosis. The increase and decrease of hormones during the menstrual cycle reasons endometrial implants to thicken, break down and bleed. Hormone medication may deliberate endometrial tissue growth and prevent new implants of endometrial tissue.

Hormone therapy isn't a permanent fix for endometriosis. It could experience a return of symptoms after stopping treatment.

AETIOLOGY

The ovarian steroids oestrogen and progesterone are intimately involved in the development of endometriosis, as evidenced by the relationship of disease activity to uninterrupted menstrual cycles, onset following menarche and transfer of disease at menopause and benefit of medical therapy which suppresses ovulation.

The histological origin of endometriosis remains controversial. Historically, suggested theories have included retrograde menstruation, lymphatic or haematogenous spread, and metaplasia

ABOUT THE PRODUCT

DIENOGEST

Mechanism of action

Central:

- Inhibition of gonadotropin secretion: moderate suppression of circulating estradiol

Local:

- Anti-proliferative
- Anti-inflammatory
- Anti-angiogenic

Dienogest defined as only low-dose progestin allowing for long-term use in endometriosis has been shown to be equally effective as GnRH-agonists, with a favorable safety and tolerability profile,

INDICATIONS AND CLINICAL USE

- **Geriatrics (> 65 years of age)**

Dienogest didn't indicate for use for geriatric population

- **Paediatrics (< 18 years of age)**

Dienogest didn't intend for use prior to menarche. The safety and efficacy of Dienogest in adolescents) has not yet been established.

CONTRAINDICATIONS

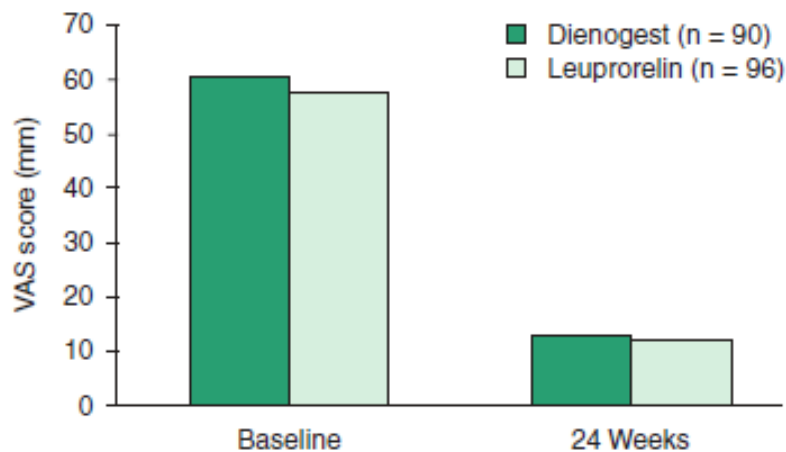
- Known or suspected pregnancy
- Lactation
- Active venous thromboembolic disorder
- Arterial and cardiovascular disease, past or present (e.g. myocardial infarction, cerebrovascular accident, ischemic heart disease)
- Diabetes mellitus with vascular involvement

- Presence & past of liver tumours (benign or malignant)
- Known or suspected sex hormone-dependent malignancies
- Abnormal undiagnosed vaginal bleeding

CLINICAL TRIALS

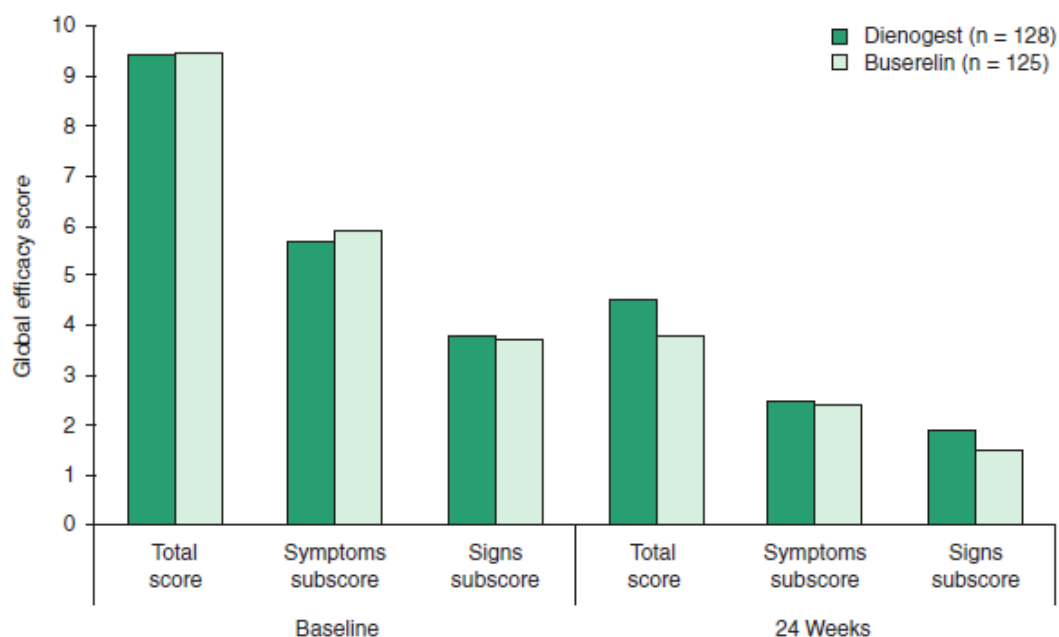
Therapeutic Efficacy

1. Comparison with Leuprorelin



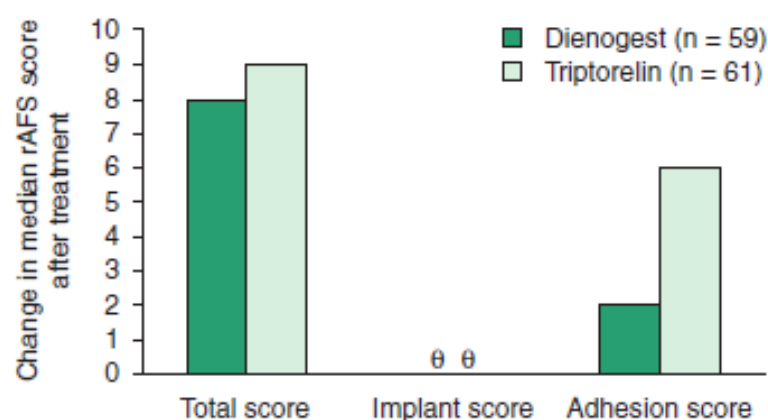
In the treatment of endometriosis, Efficacy of dienogest compared with buserelin, the sub scores for the subjective symptoms lower abdominal pain, lumbago, defecation pain, dyspareunia and pain and objective signs induration of pouch of Douglas and limited uterine mobility subgroups at baseline and after 24 weeks of treatment in the full analysis set. Results of a randomized, double-blind, controlled trial in which patients with endometriosis received oral dienogest 2mg once daily or intranasal buserelin spray 300 mg three times daily for 24 weeks. Reduced scores indicate improvement in symptoms.

2. Comparison with Buserelin



Results of a randomized, open-label, noninferiority trial in which patients with laparoscopically confirmed endometriosis received oral dienogest 2mg once daily or intramuscular leuporelin 3.75mg every 4 weeks for 24 weeks. Efficacy of dienogest compared with leuporelin in the treatment of endometriosis-associated pelvic pain. The primary efficacy endpoint was the reduction from baseline at 24 weeks in pelvic pain assessed on a 100mm visual analogue scale (VAS) in the per-protocol set. The predefined criterion for noninferiority (noninferiority margin of 15mm on the VAS) was met.

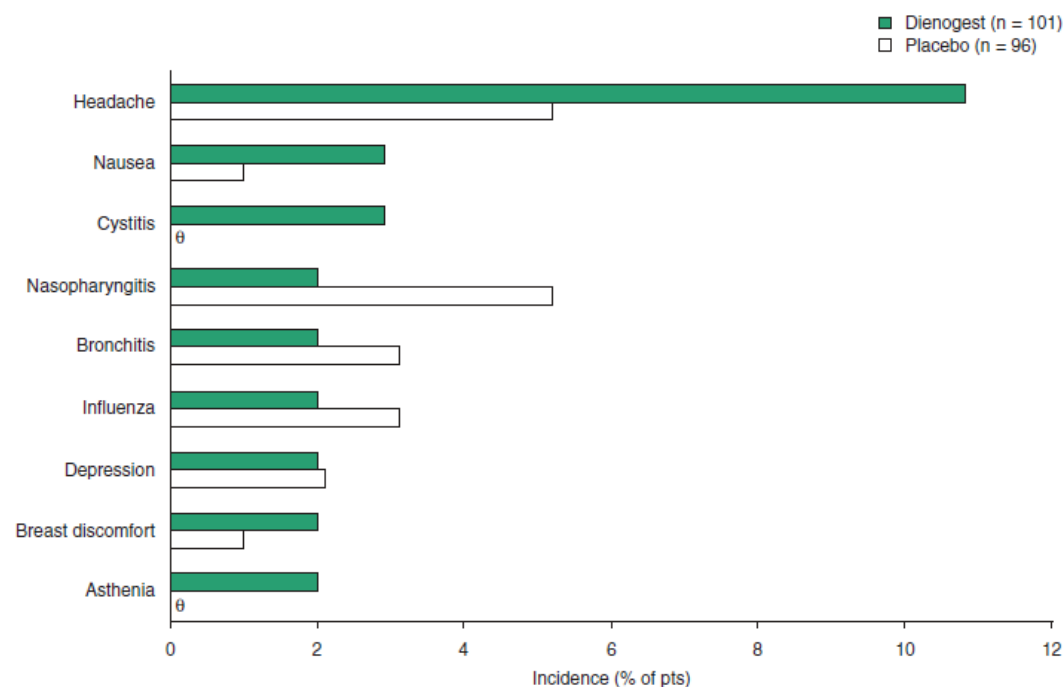
3.Comparison with Triptorelin



In the treatment of endometriosis, tolerability of oral dienogest. Adverse events reported with a frequency $\pm 2\%$ in the dienogest group in a randomized, double-blind, placebo-controlled, trial in which patients (pts)

with laparoscopically confirmed endometriosis received treatment with dienogest 2mg once daily or placebo for 16 weeks.

4.Comparison with Placebo



Efficacy of dienogest compared with triptorelin as consolidation therapy following laparoscopic surgery for endometriosis. and adhesion subscore for each treatment group between the evaluation immediately after surgery and that performed after 16 weeks of medical therapy in the per-protocol population are shown the changes in the revised classification of the American Fertility Society (rAFS) total score, implant subscore (primary endpoint). Results of a randomized, open-label, multicentre study in which patients with endometriosis undergoing laparoscopic surgery received 16 weeks of postoperative consolidation therapy with oral dienogest 2mg once daily or intramuscular triptorelin 3.75mg every 4 weeks.

OBJECTIVE

Objective of the Study

The main objective was to evaluate the role of dienogest for the treatment of endometriosis & to launch brand i.e DINOTOP.

Primary Objectives:

- To analyze the perception of dienogest among gynaecologist and its market positioning.
- To analyse the market trend and competitors.
- To understand the current available treatment for endometriosis and analyse the gap between them.

METHODOLOGY**Sample Design:**

Descriptive type of study

Sampling:

Random convenience sampling

Sample population:

Gynaecologist in two cities

Sample Size:

Total respondents: 30

Gynaecologist in Mumbai: 25

Gynaecologist in Nagpur: 5

Sample area:

Mumbai

Nagpur

Tool:

Semi-structured questionnaire was used to collect primary data

Microsoft Excel was used to carry out analysis

MIS, SMSRC & AWACS data used to collect secondary data

Data Collection:

Primary- Through semi-structured questionnaire and meeting with respondents

Secondary- To understand study topic and objectives information from various sources like articles, journals, reference books, previous relevant studies were collected.

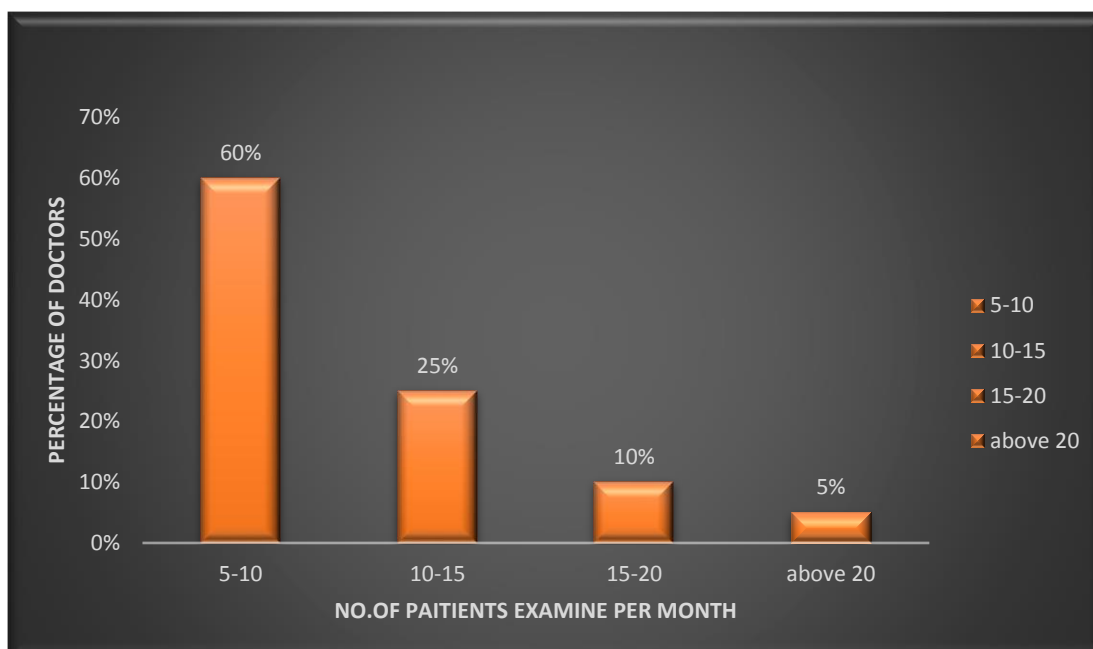
Study duration:

Three (3) months

ANALYSIS & INTERPRETATION-

1.Total number of gynaecologists examine endometriosis patients in month:

As Endometriosis is a rare disease, it was essential to know the number of patients examined by a gynaecologists in a month.



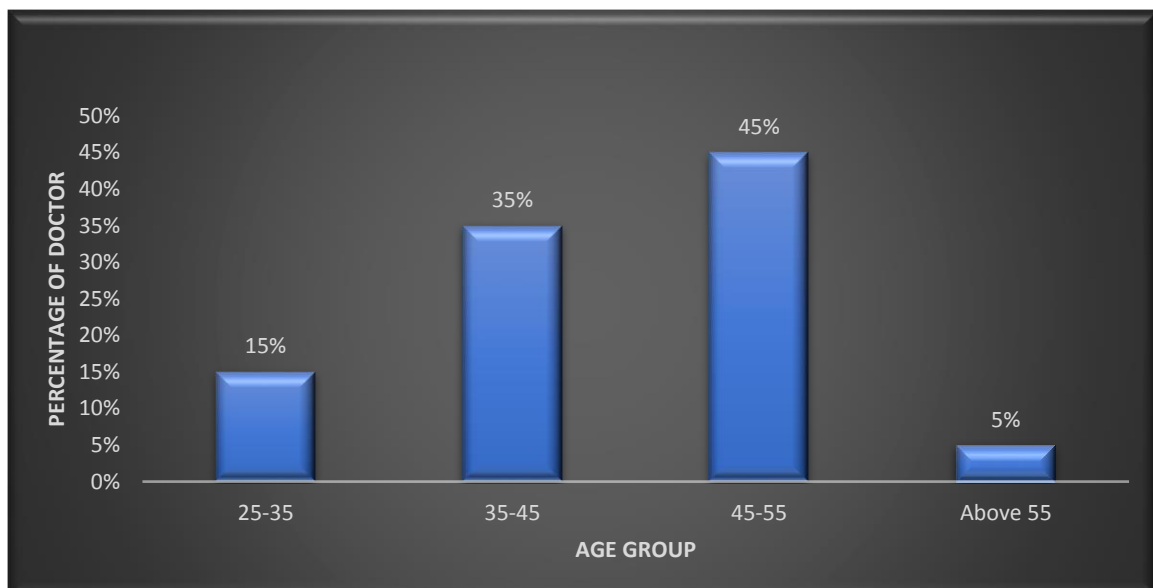
Interpretation:

From the above chart, it is clear that 60% of Gynaecologists examine 5-10 number of patients whereas 25% examine patients between 10-15.

Hence, majority of gynaecologist examine lesser number of endometriosis patients therefore the population of the disease is less in number.

It's important to note that we have not conducted Interview with doctors who do not have endometriosis patients

2. Major age group suffered by Endometriosis:

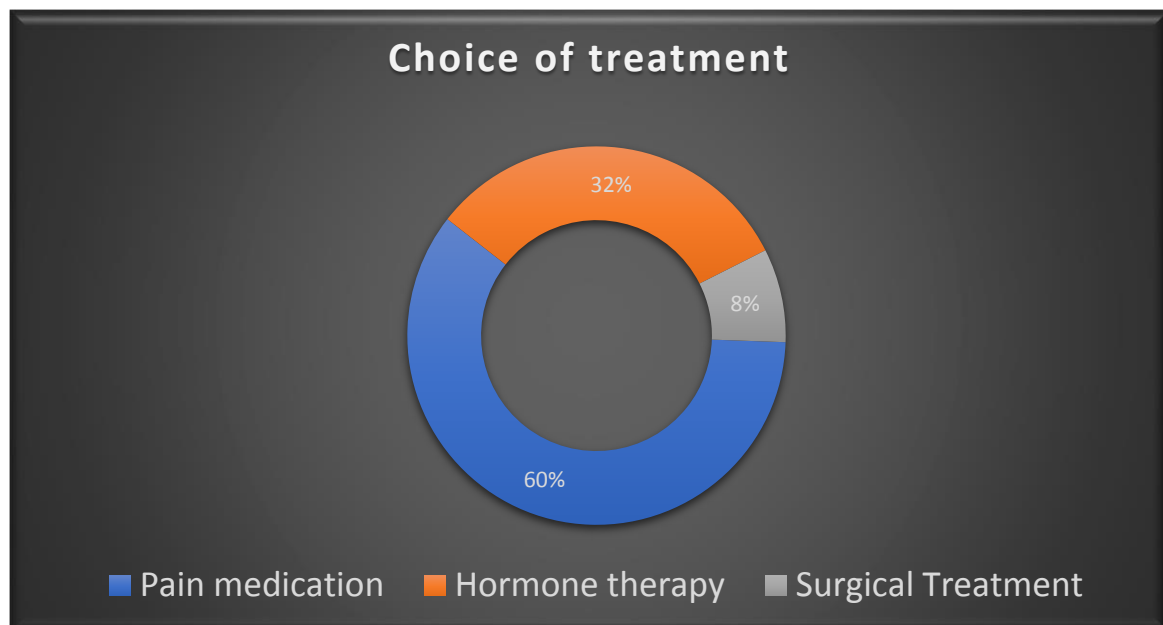


Interpretation:

From the above chart, it was found that 45% of gynaecologist examine age between 45-55 patients whereas 35% examine 35-45 age patients of endometriosis and only 15% examine 25-35 age women.

Therefore, majority of gynaecologist are going over maximum diagnose of 45-55 age group patients.

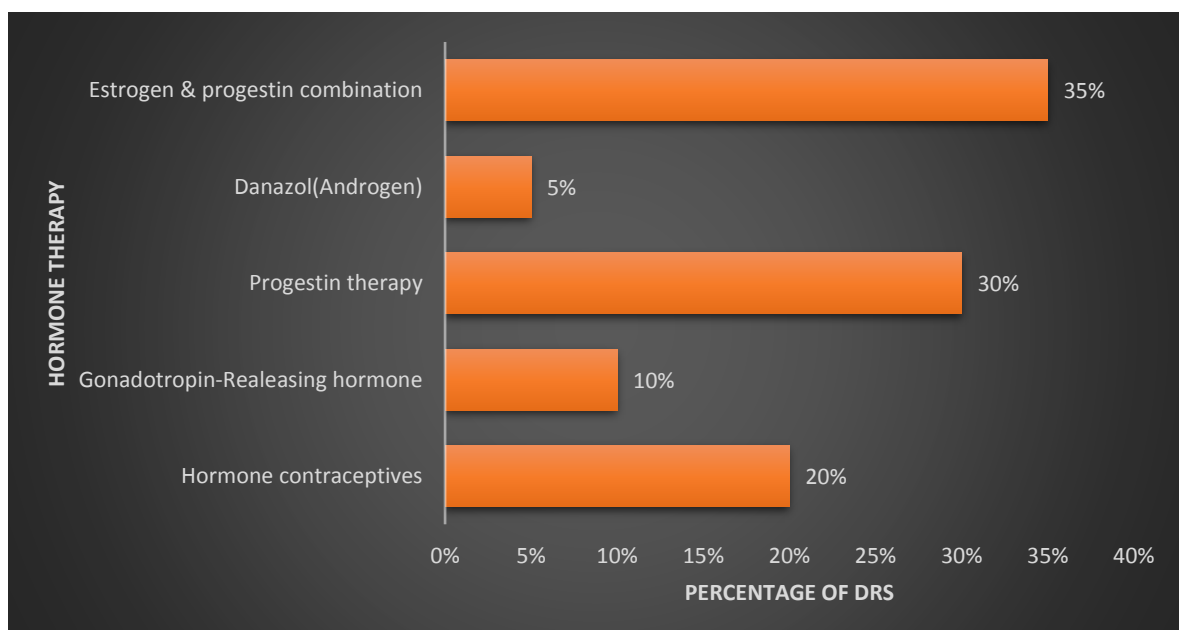
3.First choice of treatment for endometriosis:



Interpretation –

From the above graph, it shows that 60% of gynaecologist preferred pain medication as a first choice of therapy whereas 32% go for hormone therapy & 8% for surgical treatment.

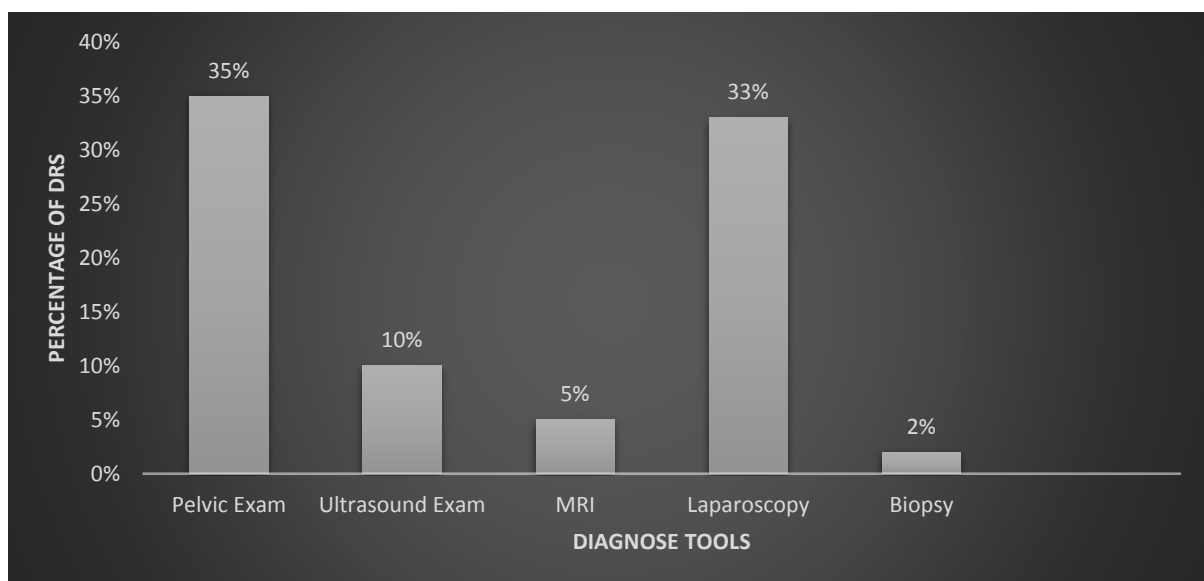
4. The most preferred hormone therapy



Interpretation –

From the above graph, it clearly seen that 35% of gynaecologist preferred Estrogen & progestin combination whereas 30% preferred only progestin therapy without any combination and 20% preferred hormone contraceptives as their third choice for hormone therapy. Therefore, it can be say that estrogen & progestion is the most preferred hormone therapy in endometriosis.

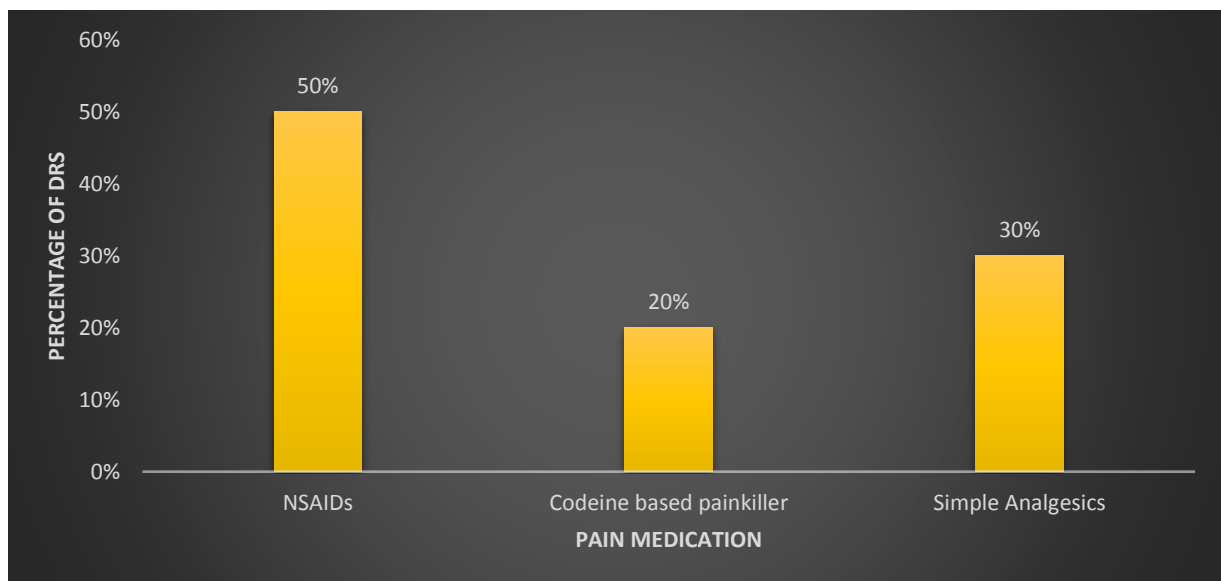
5. Most Preferred diagnose tools



Interpretation –

Majority of gynaecologist i.e. 35% are giving preference to pelvic exam, because it clearly diagnose endometriosis associated with pelvic pain ,whereas 33% gynaecologist giving second preference as laparoscopy and third preference as ultrasound which clearly diagnose the infertility related problems.

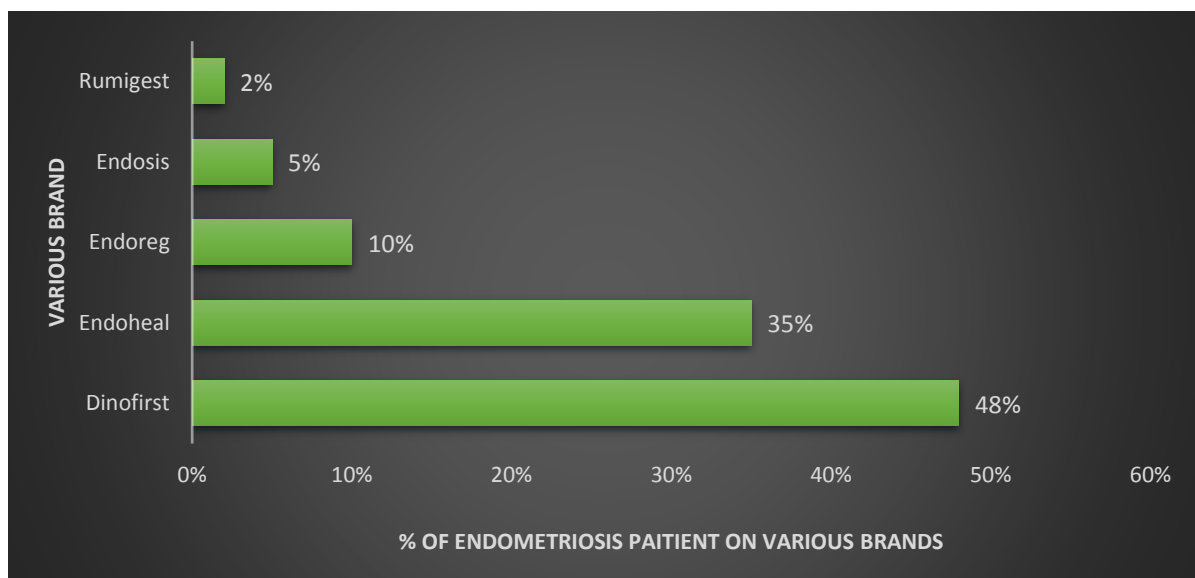
6. Most preferred pain medication in endometriosis



Interpretation –

From the above chart, it shows that 50% of gynaecologist are giving NSAIDs for the pelvic pain associated with endometriosis whereas 30% giving simple analgesics and 20% put their patients on codeine based painkiller.

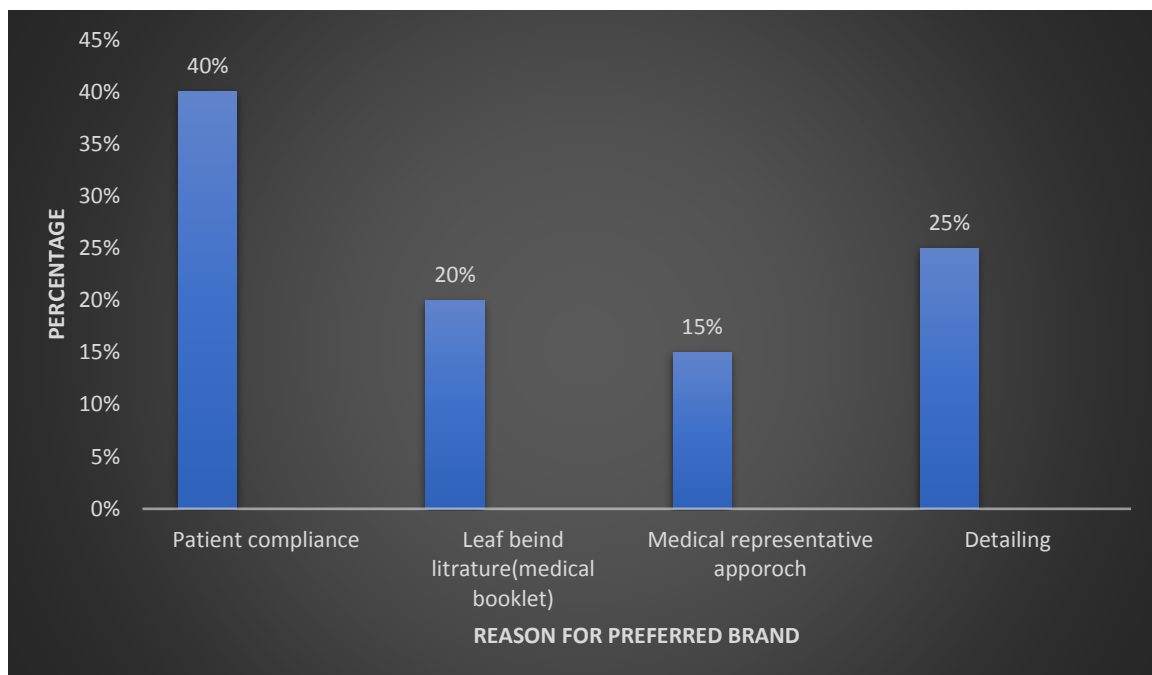
7. Existing endometriosis patients on various brand



Interpretation –

From the chart, it was concluded that majority of endometriosis patients i.e. 48% are treated by Dinofirst whereas 35% are treated with the help of Endoheal.

8.The reason for preferred brand



Interpretation-

From the above analysis, it is clearly shown that, majority of gynaecologist i.e. 40% preferred patient compliance while 25% looks forward towards detailing and 20% referred leaf behind literature which includes the medical literature about product.

9.Challenges in current treatment options:

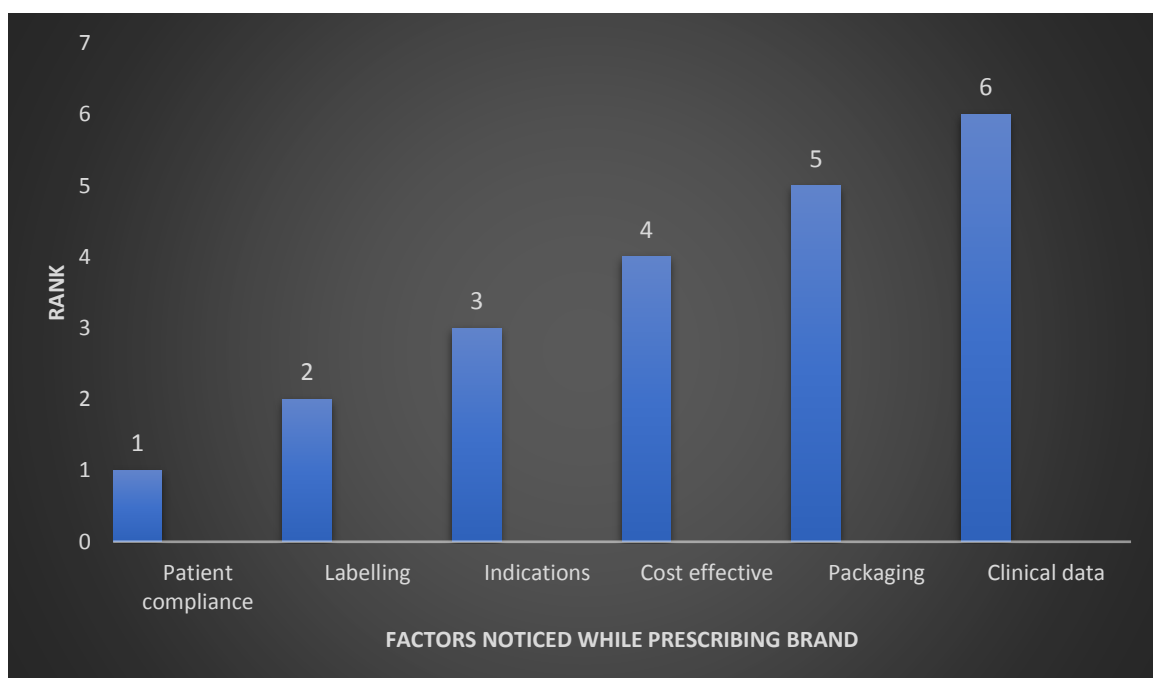
Major challenges in both the regions which Gynaecologist face in the current treatment options are as follows:

- Prohibitive cost of the therapy
- Patient compliance
- Relapse rate

10.The sign and symptoms noticed for endometriosis?

- Abnormal or heavy bleeding during periods
- Infertility
- Dyspareunia
- Dysuria
- Dysmenorrhea

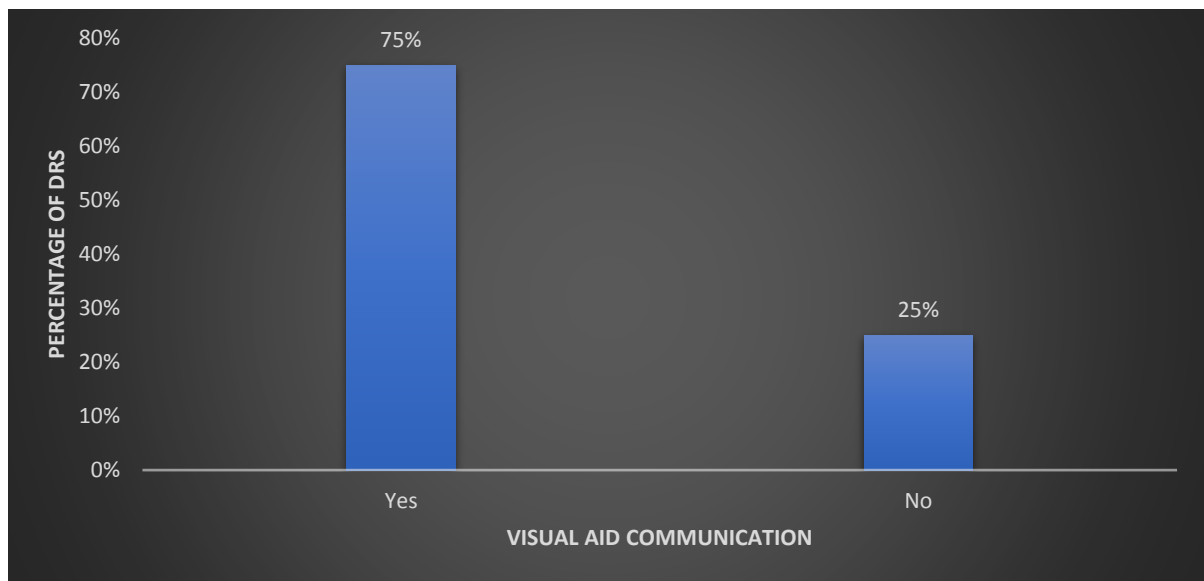
11.The crucial factors noticed while prescribing a particular brand for endometriosis? (Rate them 1-6)



Interpretation –

It seems that most of the gynaecologists has given first rank to patient compliance followed by labelling, indications, cost effectiveness and clinical data.

12.Satisfaction with visual aid communication?



Interpretation-

From above graph, majority shows that 75% gynaecologist were satisfied with visual aid communication while 25% were not satisfied they want more clinical studies in the visual aid for their more clarification about brand.

BRAND LAUNCH PLAN

1. TARGETING

- ✓ High profile Gynaecologists

2. SEGMENTATION

- ✓ Pelvic pain associated with Endometriosis

3. POSITIONING

- ✓ Pay-off line – Enjoy Top Quality of Life

4.PROMOTIONAL ACTIVITY

- ✓ Distributing FAQ related with Endometriosis
- ✓ Distributing Clinical trials data based on effectiveness of Dienogest over endometriosis
- ✓ Arranging conferences and seminars attended by Key opinion leaders in this field
- ✓ Distributing LBL over different clinics and get the response by customers
- ✓ Distributed medical booklet for product information

SWOT Analysis

1. Strength

- ✓ High quality product with distinctive features

2. Weakness

- ✓ Raw materials are less available in the market

3. Opportunity

- ✓ Untapped market
- ✓ Not much options available
- ✓ Maintain the sense of motherhood

4. Threats

- ✓ Prohibitive cost
- ✓ New launch product it may take time to grab market share
- ✓ Less awareness about endometriosis disease

PRESCRIPTION ANALYSIS: TARGET DOCTOR

	NOV-FEB 2015	MAR-JUN 2015	JUL-OCT 2015	NOV-FEB 2016	MAR-JUN 2016
DIENOGEST (S)	25	26	39	36	83
DINOFIRST TAB [AKUMENTIS HC]	25	24	30	27	33
ENDOHEAL TAB [AKUMENTIS HC]	0	0	0	0	9
ENDOSIS CAPS [PHARMA LAB]	0	0	0	4	20
ENDOREG TAB [JAGSONPAL PH]	0	0	0	1	13
DINOGEST TAB[KOYE]	0	0	0	1	6

TARGET MARKET ANALYSIS

BRAND	COMPANY	MAT VAL	MAT UNIT
DINOFIRST	AKUMENTIS	4.52	118932
ENDOHEAL	AKUMENTIS	2.29	60349
ENDOREG	JAGSONPAL	2.65	52993
ENDOSIS	PHARMANOVA	1.62	42547
RUMIGEST	ALEMBIC LTD	1.24	31014
ENDOFIT	AKUMENTIS	0.63	16504
DINOGEST	KOYE	0.40	10583
DIENOFEM	TTK	0.09	2355
DIENOGEST TOTAL MARKET		13.44	335277

COMPITITORS

BRAND	CORPORATE	MRP
DIENOFEM	TTK	480
DINOFIRST	AKUMENTIS	499
DINOGEST	KOYE	499
ENDOFIT	AKUMENTIS	499
ENDOHEAL	AKUMENTIS	499
ENDOREG	JAGSONPAL	630
ENDOSIS	PHARMANOVA	499
RUMIGEST	ALEMBIC LTD	520

VISUAL-AID COMMUNICATION





In management of
Pelvic pain associated with Endometriosis

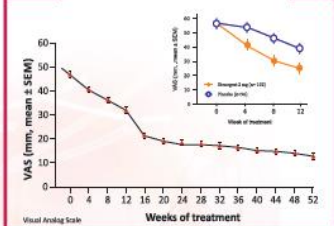
Presenting



Dienogest 2 mg Tablets

Enjoy TOP quality of Life

80% decrease in Endometriosis Pain



Visual Analog Scale

Weeks of treatment

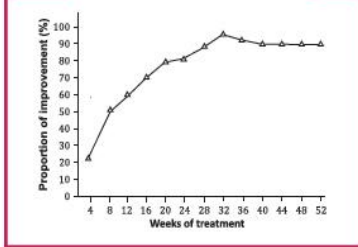
Reduces endometriotic lesions³

Reduces intensity of dyspareunia, dysmenorrhea, and diffuse pelvic pain³

Ref 3: International Journal of Women's Health 2013;3: 175-184



90% improvement in the severity of symptoms



Proportion of improvement (%)

Weeks of treatment

Symptoms

- ☞ Lower Abdominal Pain
- ☞ Dyschezia
- ☞ Lumbago
- ☞ Dyspareunia

Safe and effective for long term treatment






In management of
Pelvic pain associated with Endometriosis



Dienogest 2 mg Tablets

Enjoy TOP quality of Life

- ☞ Line of treatment for Endometriosis³
- ☞ Intensity of pain associated with endometriosis decreases significantly³
- ☞ Efficacious, Safe and tolerable³

Indication

Pelvic pain associated with Endometriosis

Dosage

Once a Day



Enjoy TOP quality of Life

Ref 3: International Journal of Women's Health 2013;3: 175-184

KEY FINDINGS-

Following findings were observed after meeting with Gynaecologist, in two cities:

- Majority of gynaecologist examine lesser number of endometriosis patients therefore the population of the disease is less in number, 60% of Gynaecologists examine 5-10 number of patients.
- Majority of gynaecologist are going over maximum diagnose of 45-55 age group patients.
- 60% of gynaecologist preferred pain medication as a first choice of therapy
- 35% of gynaecologist preferred estrogen & progestin combination.
- Majority of gynaecologist i.e. 35% are giving preference to pelvic exam, because it clearly diagnose endometriosis associated with pelvic pain
- 50% of gynaecologist are giving NSAIDs for the pelvic pain associated with endometriosis
- It was concluded that majority of endometriosis patients i.e. 48% are treated by Dinofirst(Akumentis).
- Majority of gynaecologist i.e. 40% preferred patient compliance while 25% looks forward towards detailing and 20% referred leaf behind literature which includes the medical literature about product.
- Major challenges in both the regions which Gynaecologist face in the current treatment options are as follows:
 - ✓ Prohibitive cost of the therapy
 - ✓ Patient compliance
 - ✓ Relapse rate
- Following sign and symptoms noticed in endometriosis patients-
 - ✓ Infertility
 - ✓ Dyspareunia
 - ✓ Dysuria
 - ✓ Dysmenorrhea
- Majority shows that 75% gynaecologist were satisfied with visual aid communication

❖ Positioning of new launch brand-

Pay-off line- Enjoy top quality of life.

Target- High profile gynae.

Segmentation- Pelvic pain associated with endometriosis

Promotional inputs-

- ✓ Distributing FAQ related with Endometriosis.
 - ✓ Distributing Clinical trials data based on effectiveness of Dienogest over endometriosis.
 - ✓ Arranging conferences and seminars attended by Key opinion leaders in this field.
 - ✓ Distributing LBL over different clinics and get the response by customers.
 - ✓ Distributed medical booklet for product information
-
- ❖ Market & Prescription trend-
 - ✓ Total market of Dienogest till FY'16-17 was 13.44 cr.
 - ✓ From prescription trend it was found the Dinofirst brand is leading in the market of Akumentis .

CONCLUSION-

Delcure Lifesciences Ltd. has been appreciating the long run of its monotonous market in terms of its product. With the new product launch Dinotop, it wouldn't be wrong to say that company will enjoy the analogous situation, if price being the competitive factor.

With the Dienogest occupying the maximum market shares in Endometriosis category; it would be easy to be replaced by Dinotop. Since, Prior to its launch and clinical use of Dienogest has been well positioned as Dinofirst. Hence, it has good positioning in terms of need of extended life and less frequent dosing.

Dienogest being one of the safest molecule and ease of administration amongst the endometriosis disease available in the market, it can pick up in the market quiet well. But in the research, it has been found that 'uniqueness' and 'Supportive clinical evidence' are the most important characteristics that doctor seek before prescribing it.

Hence, it can be considered that the market condition and initial opinion about the product is ideal for the launch of Dinotop.

ANNEXURE

1.How many Patients of endometriosis do you diagnose in a month?

- ☐ 5-10
- ☐ 10-15
- ☐ 15-20
- ☐ Above 20

2.Which age group patients generally diagnosed for endometriosis?

- ☐ 25-35
- ☐ 35-45
- ☐ 45-55
- ☐ Above 55

3.What is your first choice of treatment for endometriosis?

- ☐ Pain medication
- ☐ Hormone therapy
- ☐ Surgery treatment

4.In pain medication, what do you mostly prescribed for endometriosis patients?

- ☐ NSAIDs
- ☐ Codeine based painkiller
- ☐ Simple analgesics

5.In hormone therapy, what is your line of treatment?

- ☐ Estrogen & progestin combination
- ☐ Danazol(Androgen)
- ☐ Progestin therapy
- ☐ Gonadotropin releasing hormone
- ☐ Hormone contraceptives

6.How do you diagnose endometriosis?

- ☐ Pelvic exam
- ☐ Ultrasound exam
- ☐ MRI
- ☐ Laproscopy
- ☐ Biopsy

7. Which of the following brands do you prescribed for endometriosis?

- ☐ Dienofirst
- ☐ Rumigest
- ☐ Endoheal
- ☐ Endoreg
- ☐ Endosis

8. What are the reason for preferred brand?

- ☐ Patient compliance
- ☐ Leaf behind literature (medical booklet)
- ☐ Medical representative approach
- ☐ Detailing

9. What are the crucial factors noticed while prescribing a brand for endometriosis? (Rate them 1-6)

- ☐ Patient compliance
- ☐ Labelling
- ☐ Indication
- ☐ Cost effective
- ☐ Clinical trials

10.What are the challenges in the current treatment options?

- ☐

11.What are the sign and symptoms noticed in the endometriosis patients?

- ☐

12.Do you satisfied with visual aid communication?

- ☐ Yes
- ☐ No

REFERENCES-

1. Koss SL, Peters RK, Xiang A, Buchanan TA. Contraception and the risk of type 2 diabetes mellitus in Latina women with prior gestational diabetes mellitus. *Jama*. 1998 Aug 12;280(6):533
2. McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. *Contraception*. Dec;50S1-195
3. Back DJ, Orme ML. Pharmacokinetic drug interactions with oral contraceptives. *Clinical Pharmacokinetic*. Jun;18(6):472-84
4. Olive DL, Pratt's EA. Treatment of endometriosis. 2001; 345:266-75. Giudicca LC. Endometriosis. *N Engl J Med* 2010 Jun 24; 362 (25): 2389-98
5. Cr.esignani P, Olive D, Bergvliet A, Luciano A. With Advances in the management of endometriosis: an update for clinicians. *Hum Reprod Update* 2006; 12:179-89
7. World Endometriosis Research Foundation. Available from <http://www.endometriosisfoundation.org/> Accessed 2010 Oct
8. European network on endometriosis. Available from URL: <http://www.endonetwork.eu/> [Accessed 2010 Oct
9. European Society of Human Reproduction and Embryology. ESHRE guideline for the diagnosis and treatment of endometriosis Accessible from <http://guidelines.endometriosis.org/index.html> Accessed 2010 Oct