

Evaluating the role of Dienogest in Endometriosis and Prepare Brand Launch Plan

BY-

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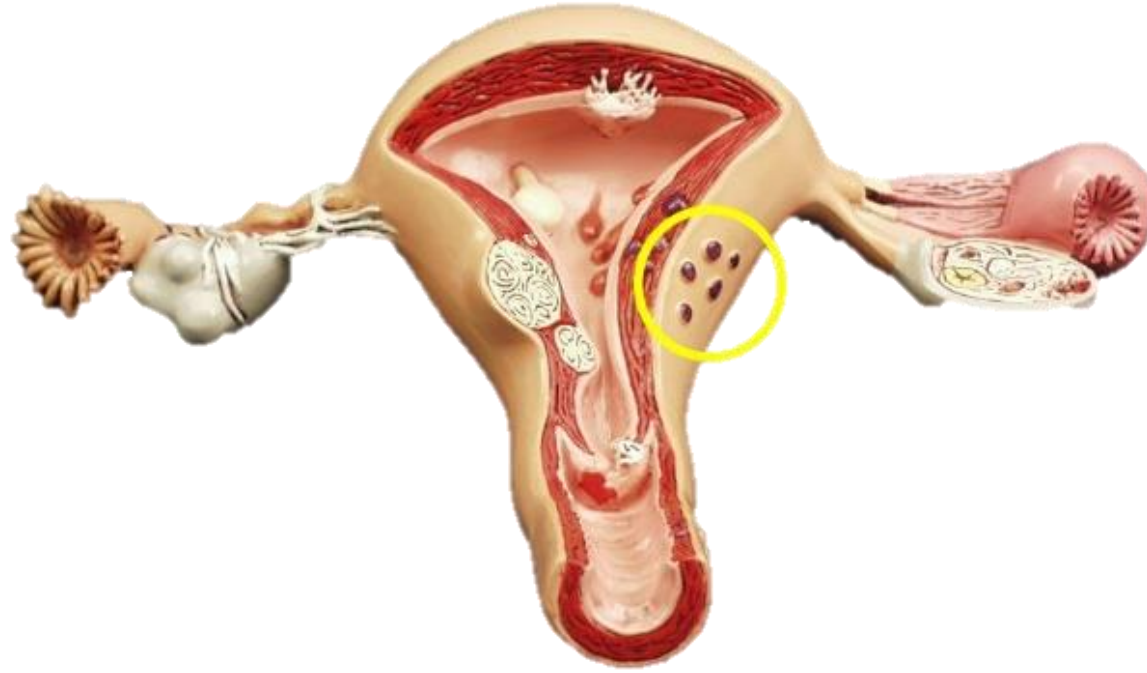
MBA-PM-07

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Endometriosis



Occurrence of *ACTIVE* endometrial tissue outside the endometrial cavity, which induces a chronic inflammatory reaction...

...**Leading to**

- Painful Symptoms
- Fatigue
- Infertility



Prevalence of endometriosis in India



1 in 50 women suffer from endometriosis



Women with endometriosis during the prime years of their lives...



Pathogenesis

Implantation theory : Endometriosis to reflux of menstrual endometrium through the fallopian tubes.

Coelomic metaplasia theory : Endometriosis arises as a result of metaplastic changes in embryonic cell rests of embryonic mesothelium.

Metastatic theory : embolization of menstrual fragments through vascular or lymphatic channels, explain its occurrence at less accessible sites



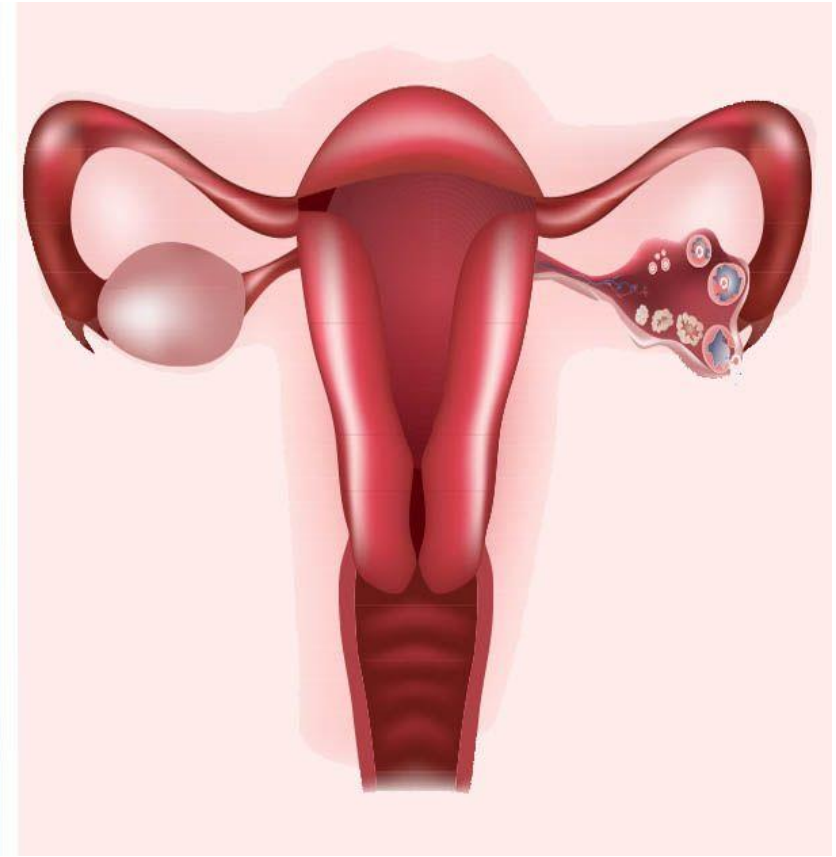
Clinical Picture

Common symptoms:

- Infertility.
- Pain Pelvic pain.
- Dysmenorrhea
- Dyspareunia
- Dysuria

Less common symptoms

- Haematuria
- Rectal pain



Women with endometriosis frequently experience symptoms of dysmenorrhea, premenstrual pain, dyspareunia, and chronic fatigue



Treatment

The main aims of treatment are

- Alleviate pain and other symptoms
- Reduce endometriotic lesions
- Improve the quality of life

Surgery

- Surgery can provide pain relief and enhance Fertility
- High risk of recurrence, which attains a rate of 40%–50% at five years



Medical Therapy

- **NSAID:** Limitation of long term and significant side effect
- **Gonadotropin-releasing hormone :** Treatment limited to 6 Mths
- **Combined oral contraceptive :** Bleeding
- **Danazol :** adverse effects on lipid metabolism and by weight Gain
- **Progestin (Dienogest) :** Effective in Long term treatment



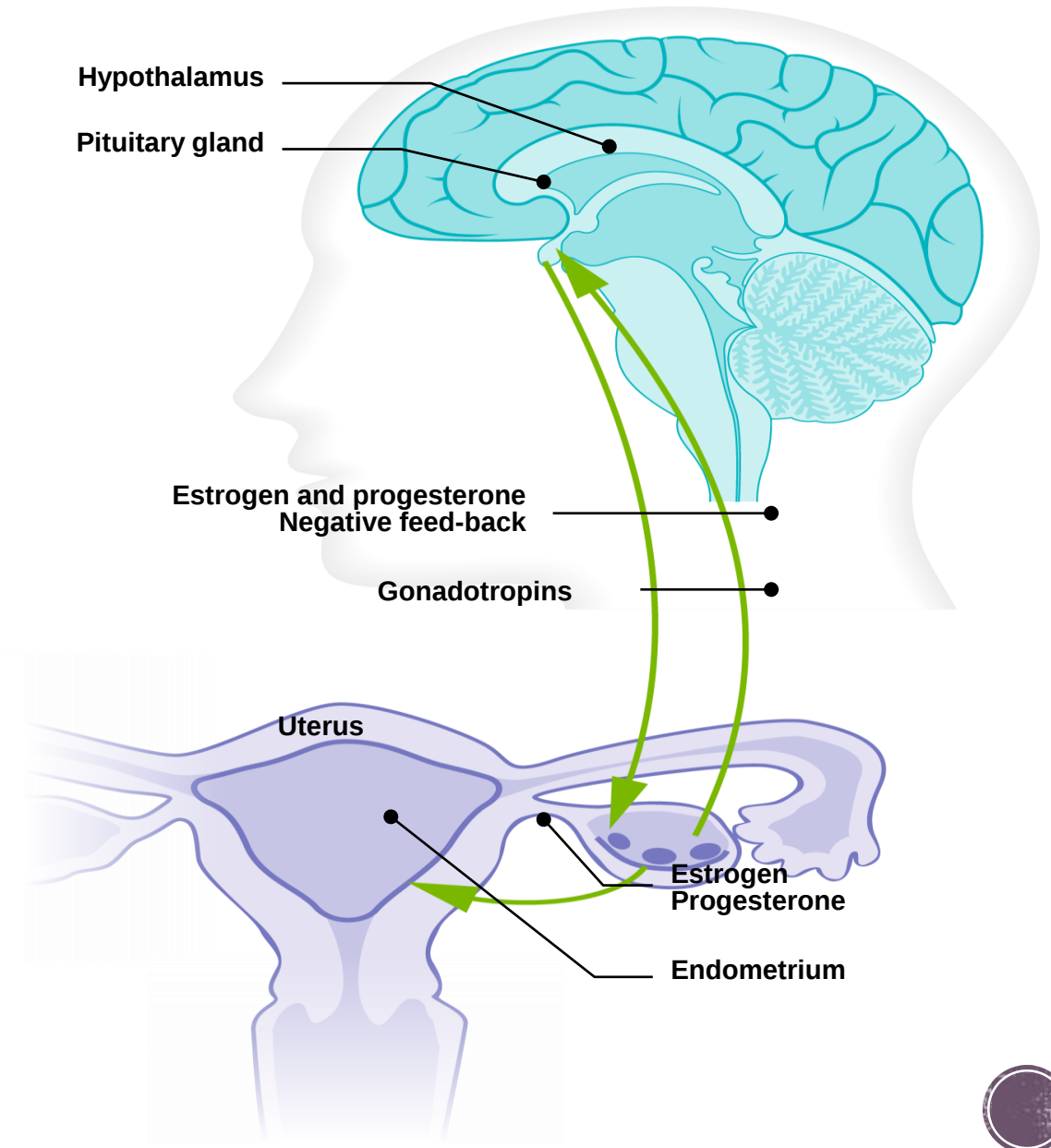
Dienogest: mode of action

Central effects

- Inhibition of gonadotropin secretion: moderate suppression of circulating estradiol
 - Ovarian function: anovulation (2 mg dose)

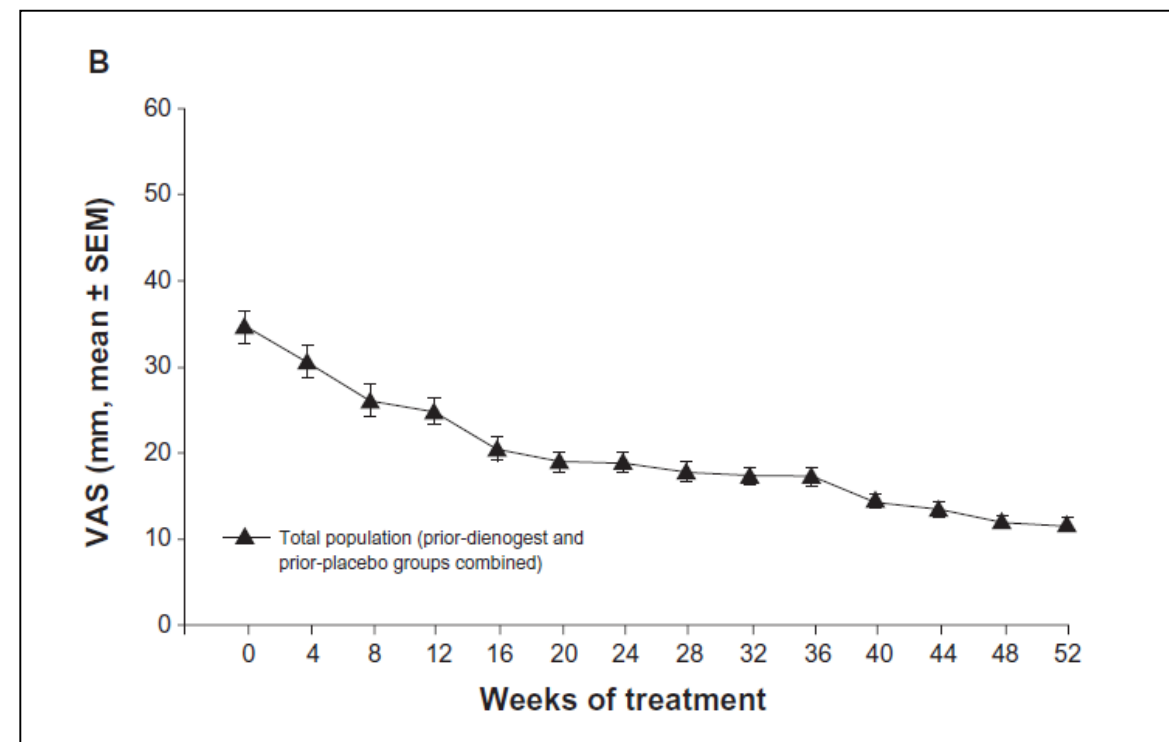
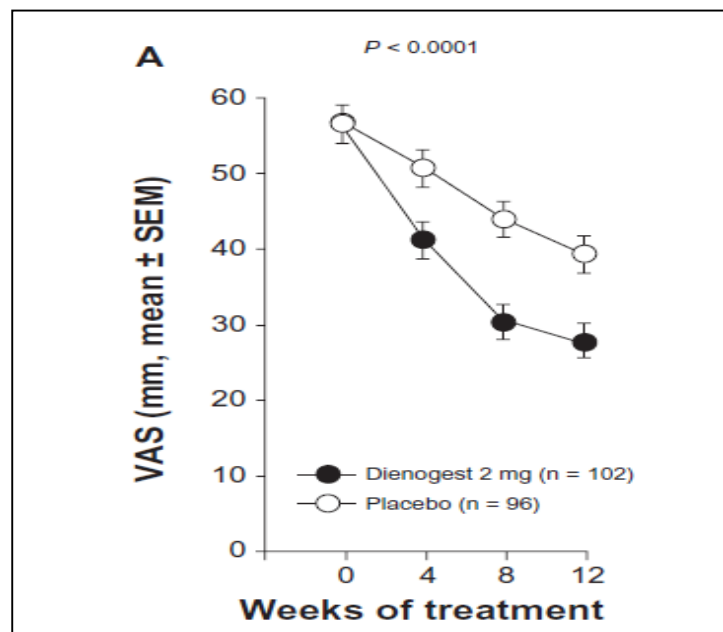
Local effects

- Anti-proliferative
- Anti-inflammatory



Effective Pain Relief

188 women where given Dienogest for 12 Weeks + 53 Weeks = 65 Weeks



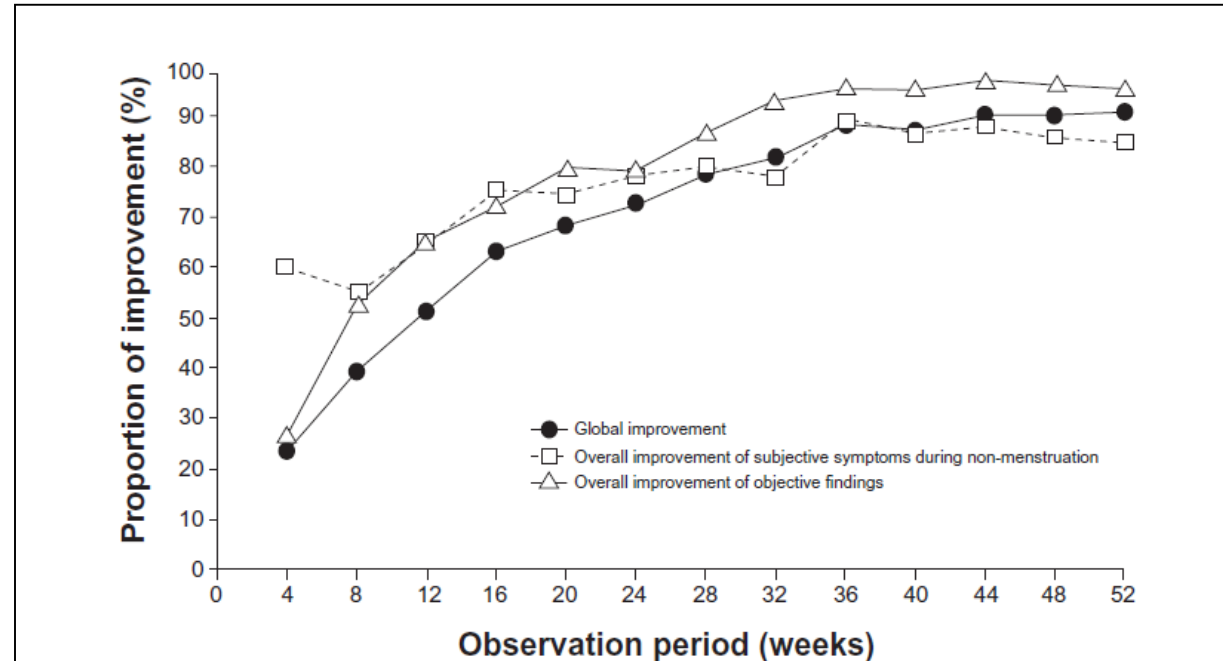
- 80% Decrease in Endometriosis Pain

- Mean visual analog scores decreased from 56.9 mm to 34.1 to 11.5 mm at the end of the 53 additional weeks of treatment



90% improvement in the severity of symptoms

Study performed in Europe. 135 Women were included in the Trial.



- Global improvement was recorded in 72.5% of patients after 24 weeks and in 90.6% after 52 weeks of dienogest treatment
- Five subjective symptoms (lower abdominal pain, lumbago, dyschezia, dyspareunia, and pain on vaginal examination)



Administration

- 2mg once-daily
- Can start at any day of menstrual cycle
- Must be continued regardless of vag. Bleeding
- Hormonal contraception should be stopped before starting Dienogest

Dienogest & Pregnancy

- Dienogest should not be administered to pregnant women because there is no need to treat endometriosis during pregnancy.



Conclusion

- DNG represents a promising new medication for safe and effective long-term management of pain of endometriosis.



Objective

- The main objective was to evaluate the role of dienogest in 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 ,prescription trend and competitors.
- To understand the current available treatment for endometriosis and analyse the gap between them.



Methodology

Sample Design:

- Descriptive study

Sampling:

- Random 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

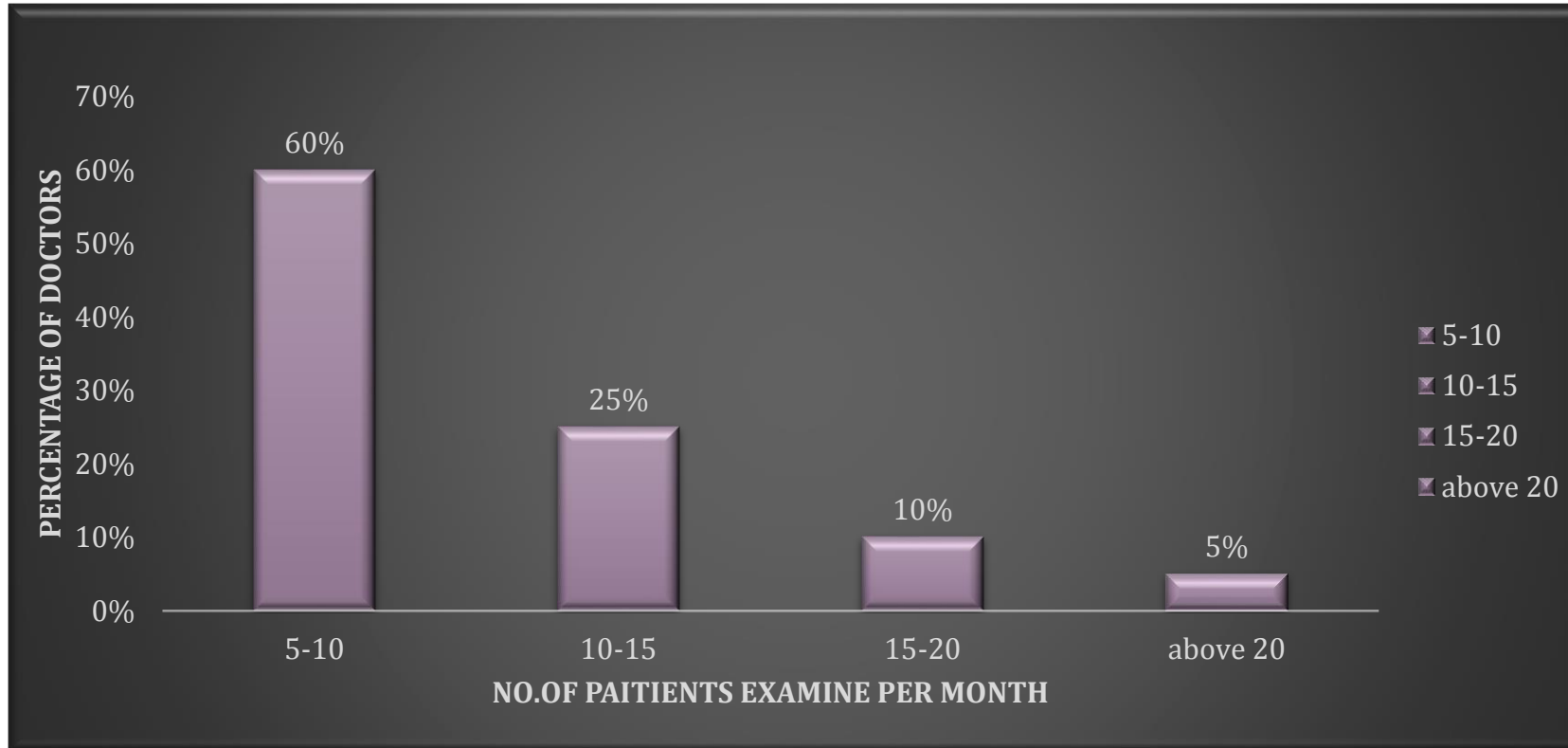




ANALYSIS AND INTERPRETATION



Total number of gynaecologists examine endometriosis patients in a month



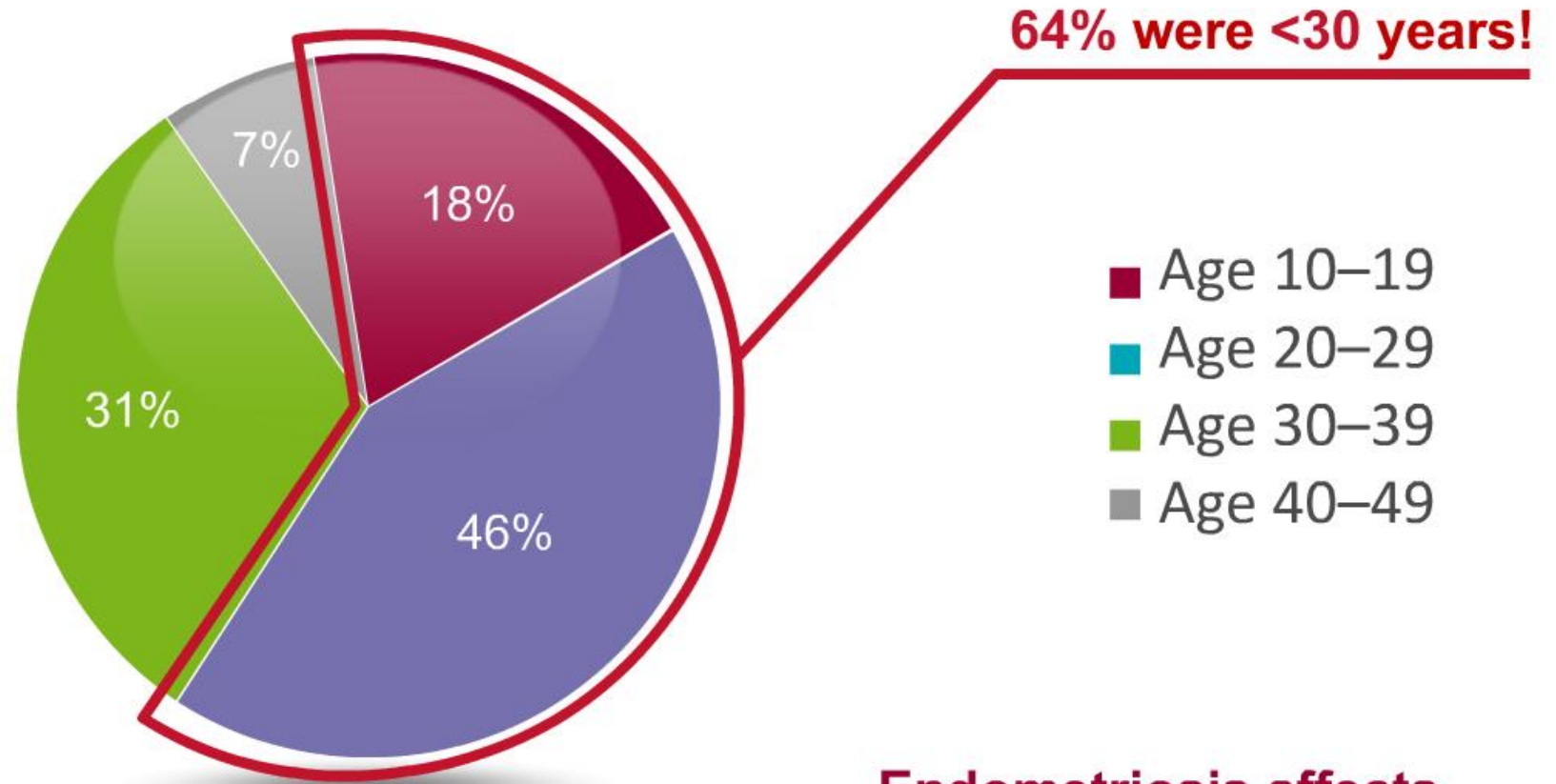
As Endometriosis is a rare disease, it was essential to know the number of patients examined by a gynaecologists in a month.

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.



Major age group suffered from endometriosis



Endometriosis affects women during the prime years of their lives!

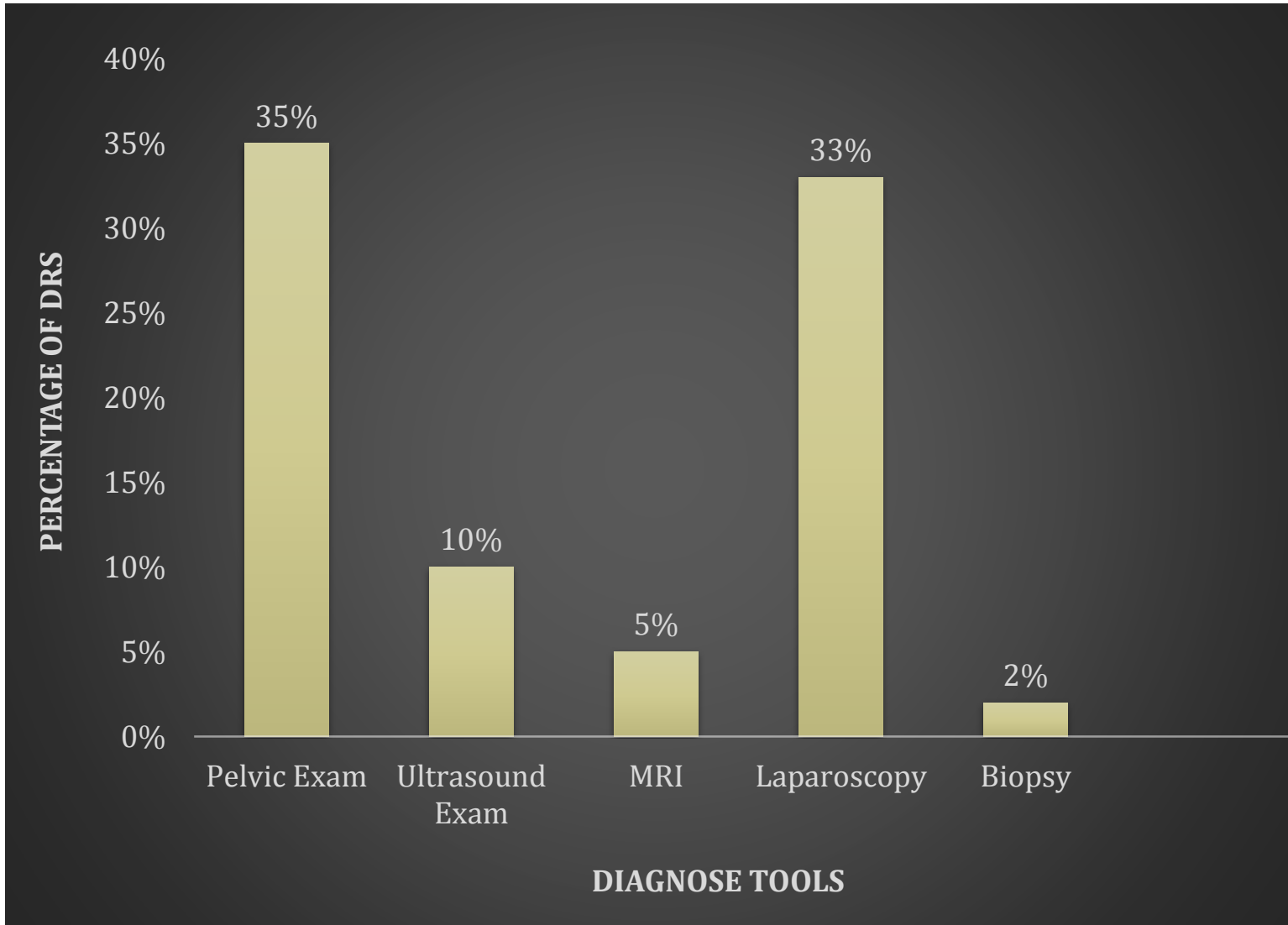


Sign and symptoms noticed for endometriosis

- Painful bowel movements or urination, especially during menstruation.
- Abnormal or heavy bleeding during periods.
- Infertility
- Dyspareunia
- Dysuria
- Dysmenorrhea



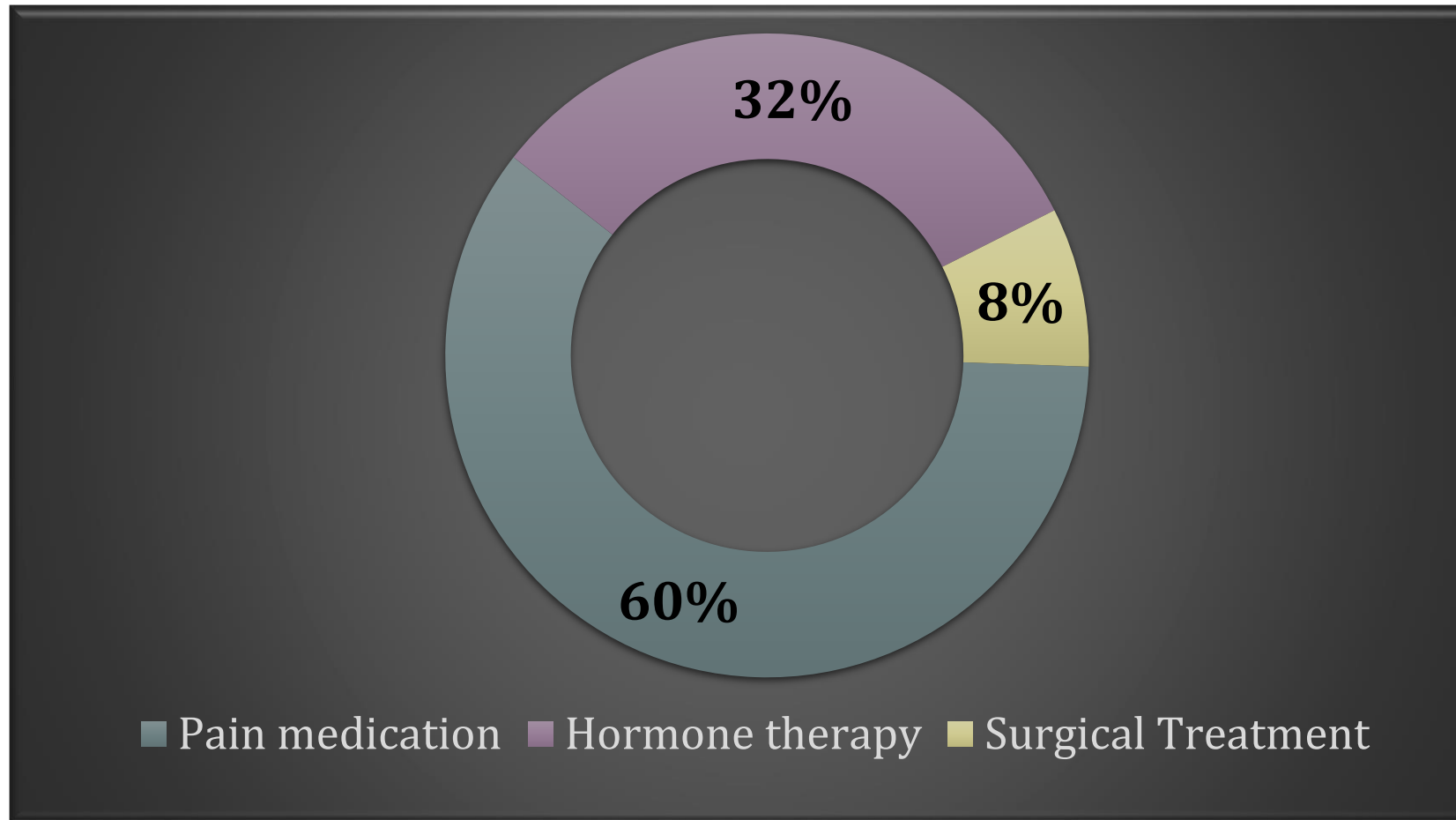
Most Preferred diagnose tools



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.



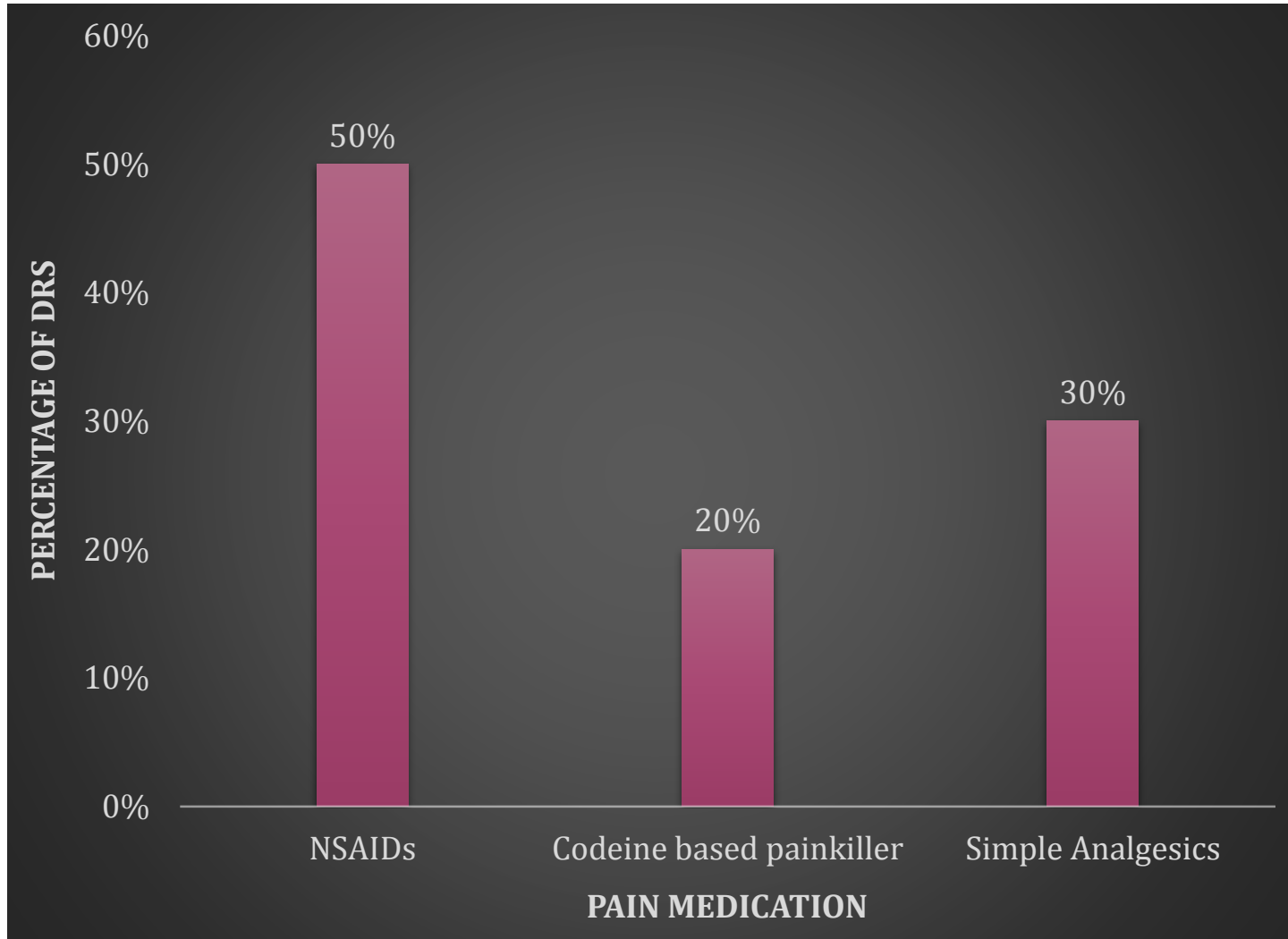
Choice of treatment for endometriosis



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.



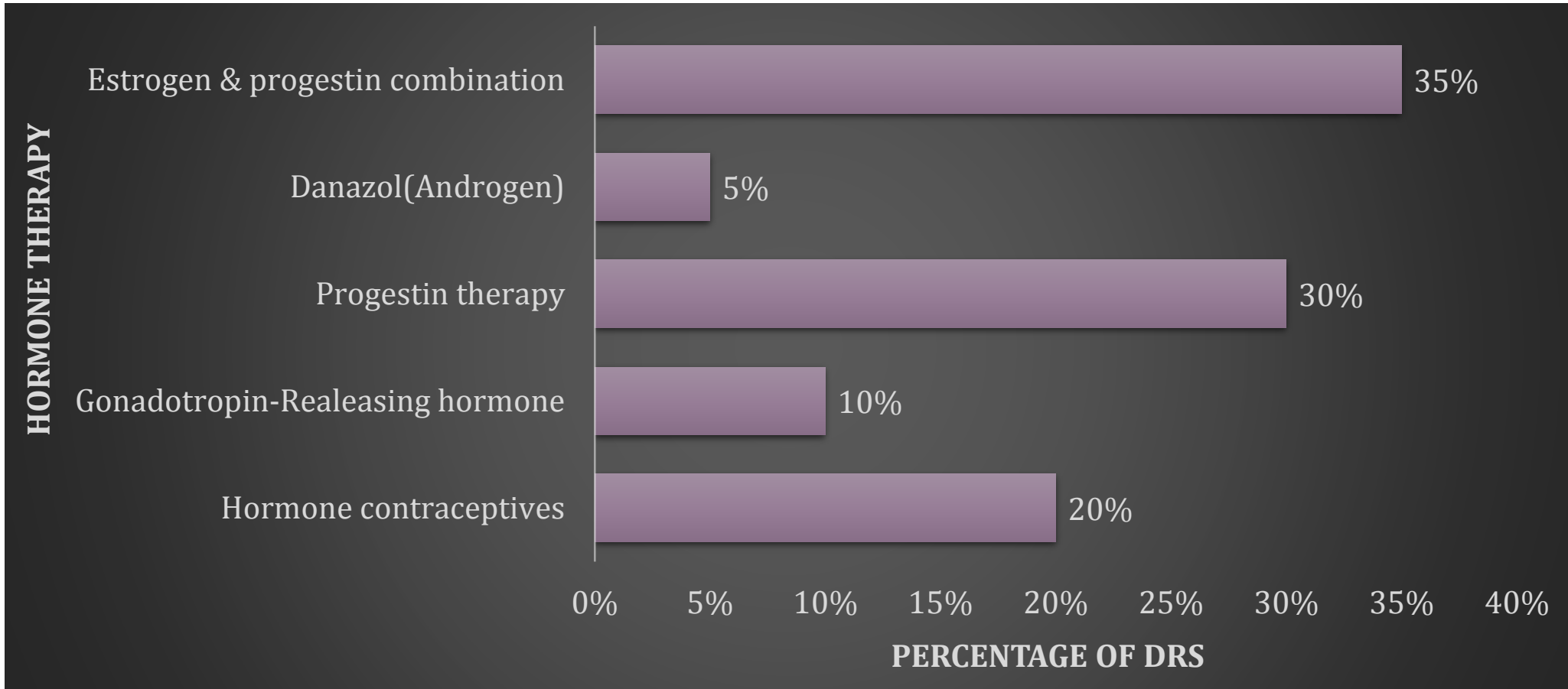
Most preferred pain medication in endometriosis



It shows that 50% of gynaecologists are giving NSAIDs for the pelvic pain associated with endometriosis whereas 30% giving simple analgesics and 20% put their patients on codeine based painkiller.



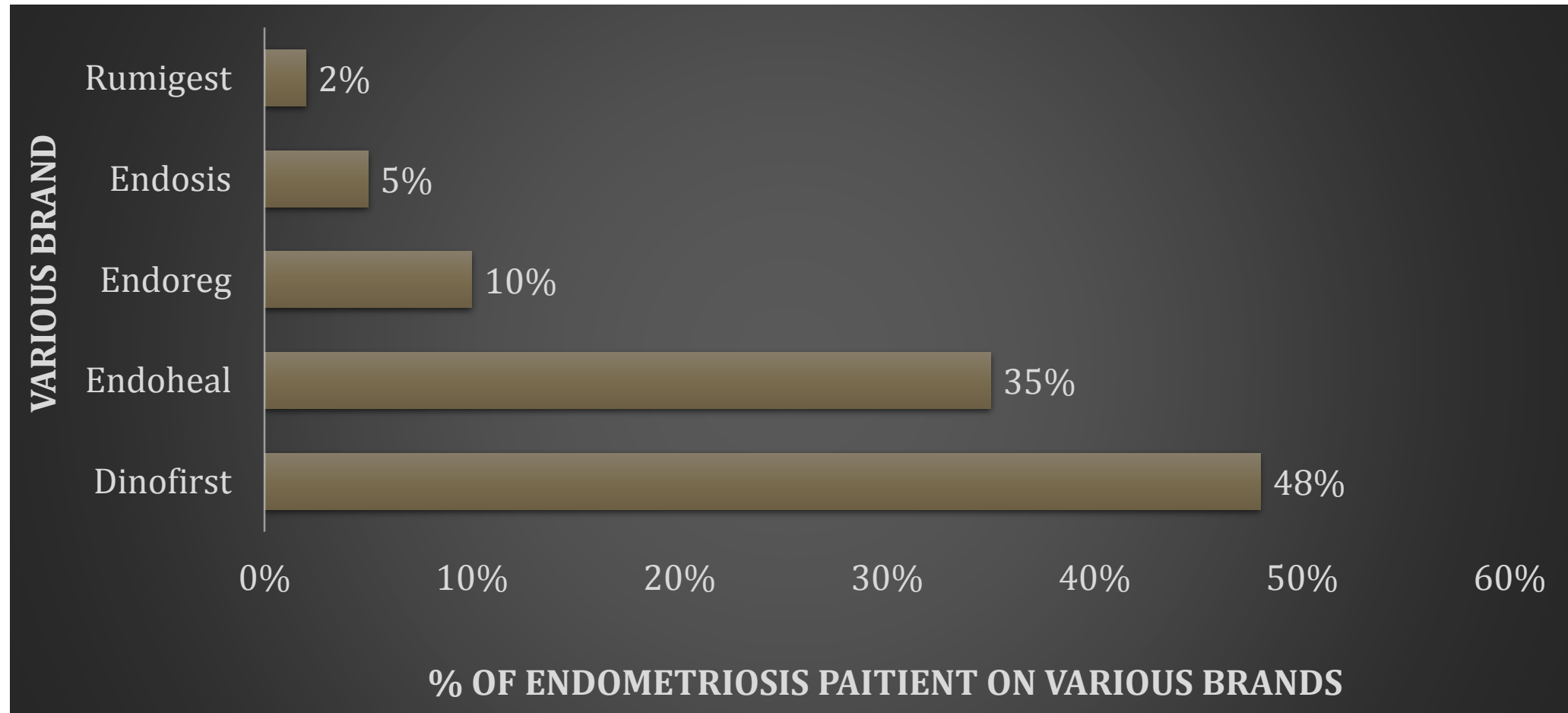
Most preferred hormone therapy



It clearly seen that 35% of gynaecologist preferred Estrogen & progestin combination whereas 30% preferred only progestin therapy without any combination. Therefore, it can be say that estrogen & progestin is the most preferred hormone therapy in endometriosis.



Existing endometriosis patients on various brand



It was concluded that majority of endometriosis patients i.e. 48% are treated by **Dinofirst** brand of Akumentis has strong foothold with Dienogest among Gynaec whereas 35% are treated with the help of Endoheal.



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



God's valuable creation...

WOMEN



...Bold, Brave & Beautiful



But Women health issue impacts QOL

To Enjoy **TOP** quality of Life



In management of
Pelvic pain associated with Endometriosis



DINOTOP

Dienogest 2 mg Tablets

Enjoy **TOP** quality of Life



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

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 MARKET TOTAL		13.44	335277

13.44 Cr Market



BRAND

- Reduces Pain of Deep Infiltrating Endometriosis
- Effectively alleviates the painful symptoms of endometriosis
- Reduces endometriotic lesions
- Improves indices of quality of life
- High rates of patient compliance
- Low withdrawal rates
- Safety used long term treatment



BRAND

OBJECTIVE

**Targeted Gynaec should
prescribe and availability of
Dinotop at all Chemist**



PRESCRIPTION ANALYSIS: TARGET DOCTOR

	NOV-FEB 2015	MAR-JUN 2016	JUL-OCT 2016	NOV-FEB 2016	MAR-APRIL 2017
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

- Prescribed by Gynaec
- Akumentis has strong foothold with Dienogest among Gynaec



POSITIONING

In management of



Pelvic pain associated with Endometriosis

Pay

Of line

Enjoy **TOP** quality of Life



Price:

BRAND	PACK	M.R.P	PTS
DINOTOP	1*10	499	338.94



Competitor Price:

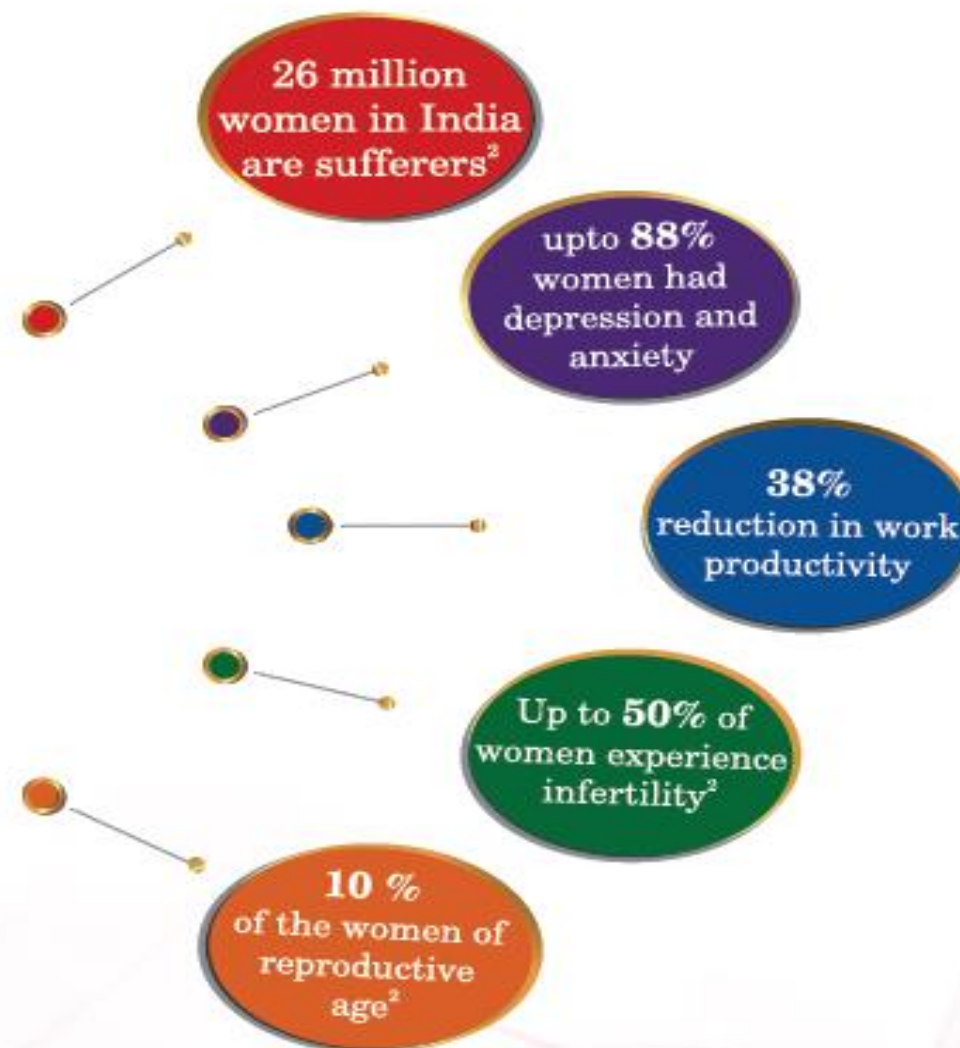
BRAND	CORPORATE	MRP
DIENOFEM	TTK	480
DINOFIRST	AKUMENTIS	499
DINOGEST	KOYE	499
ENDOFIT	AKUMENTIS	499
ENDOHEAL	AKUMENTIS	499
ENDOREG	JAGSONPAL	630
ENDOSIS	PHARMANOVA	499
RUMIGEST	ALEMBIC LTD	520



VISUAL AID COMMUNICATION



Endometriosis – A growing concern ¹



In management of
Pelvic pain associated with Endometriosis

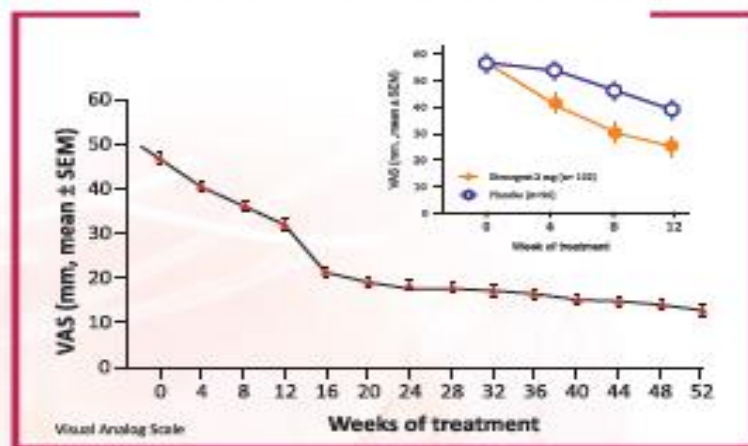


DINOTOP

Dienogest 2 mg Tablets

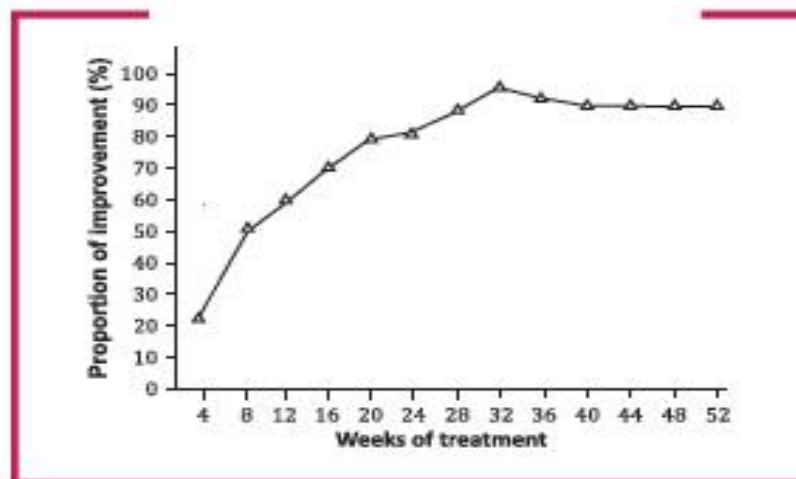
Enjoy **TOP** quality of Life

80% decrease in Endometriosis Pain



- ☞ Reduces endometriotic lesions³
- ☞ Reduces intensity of dyspareunia, dysmenorrhea, and diffuse pelvic pain³

90% improvement in the severity of symptoms



Symptoms

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

**Safe and effective for
long term treatment**



In management of
Pelvic pain associated with Endometriosis

 **DINOTOP**

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

KEY FINDINGS

- DNG represents a promising new medication for safe and effective long-term management of pain of endometriosis.
- Majority of gynaecologist examine lesser number of endometriosis patients therefore the population of the disease is less in number.
- Endometriosis affects women in their prime stage of lives.
- Sign and symptoms noticed in endometriosis patient are following-
 - ✓ Infertility
 - ✓ Dyspareunia
 - ✓ Dysuria
 - ✓ Dysmenorrhea
- Majority of gynaecologist i.e. 35% are giving preference to pelvic exam, because it clearly diagnose endometriosis associated with pelvic pain
- 60% of gynaecologist preferred pain medication as a first choice of therapy.
- 35% of gynaecologist preferred Estrogen & progestin combination whereas 30% preferred only progestin therapy without any combination
- It was concluded that majority of endometriosis patients i.e. 48% are treated by **Dinofirst** brand of Akumentis has strong foothold with Dienogest among Gynaec.
- Major challenges face in the current available treatment are-
 - ✓ Prohibitive cost of the therapy
 - ✓ Patient compliance
 - ✓ Relapse rate



Market ,Competitors & Prescription trend-

- ✓ Total market of Dienogest till FY'16-17 was **13.44 cr.**
- ✓ From prescription trend it was found that **Dinofirst** brand is leading in the market of Akumentis healthcare.
- ✓ Competitors are following brands-
 - Dinofirst (Akumentis)
 - Endoreg(Jasnogpal)
 - Endoheal(Akumentis)
 - Endofit(Akumentis)





Thank you for Top Quality of Life with Dinotop

