A STUDY ON EFFECTIVENESS OF ULIPRISTAL ACETATE FOR THE TREATMENT OF UTERINE FIBROIDS.

BY:

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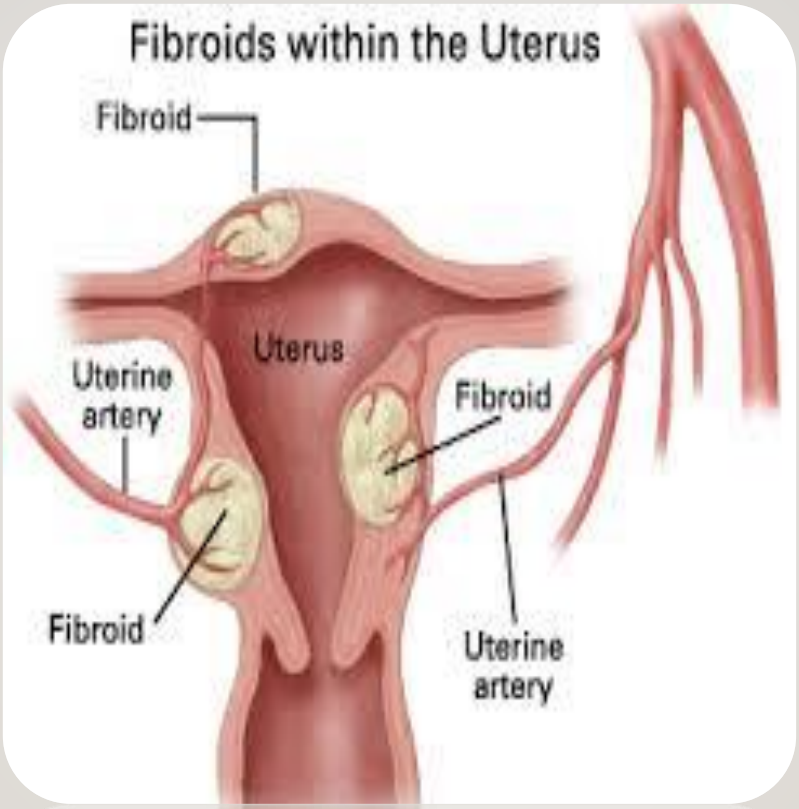
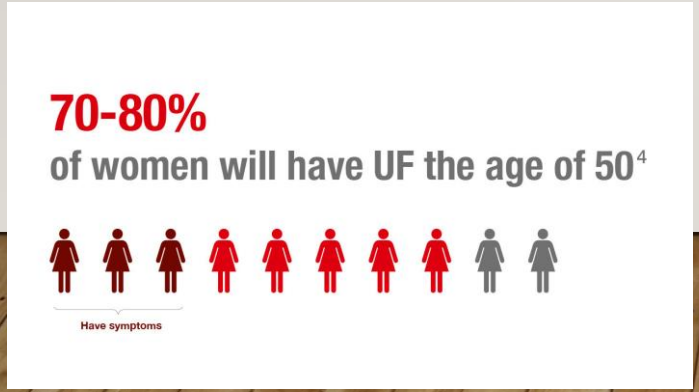
WHAT ARE FIBROIDS ???



- ✓ **Uterine fibroids are the benign Tumors of smooth muscle cells of uterus**
- ✓ Most common benign tumor of female genital tract.
- ✓ **Other names :**Leomyomas,Myomas,Fibromyomas

EPIDEMIOLOGY

- 20-40% of women suffer from Uterine fibroids in their reproductive age
- At any given time, nearly **15 - 25 million** Indian women have fibroid uterus.



Ref:www.ncb.nlm.in

What is the cause of fibroids ?

- Age
- Hormonal Imbalance
- Obesity
- Hypertension
- Family History
- Genetics

SYMPTOMS

- Heavy menstrual bleeding
- Anaemia
- Abdominal pain
- Enlarged abdomen
- Infertility

TREATMENT OPTIONS

MEDICINES

- **NSAIDs**
- **Oral Contraceptives**
- **SPRM**

SURGICAL PROCEDURES

- **Hysterectomy**

Limitations of Currently used Pharmacological Treatment

May increase in the size of fibroids

Breakthrough bleeding

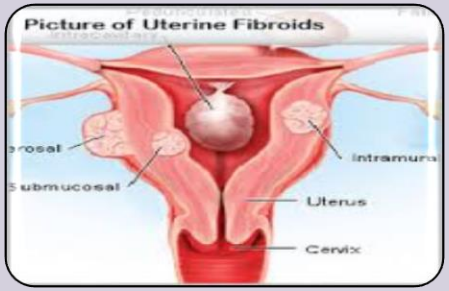
Leads to loss of motherhood

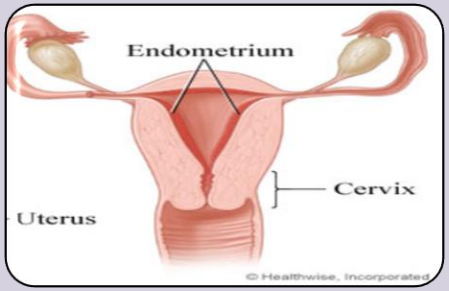
Not everyone comfortable for it

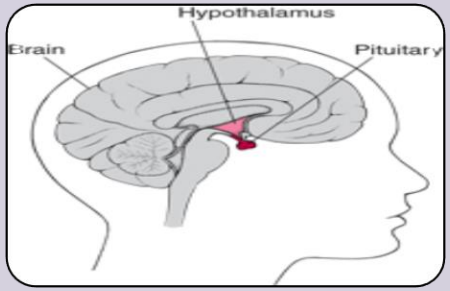
Introducing

The **1st & only medication** indicated for the treatment of Uterine fibroids &
alternative to **Hysterectomy** in adult women of reproductive age

MECHANISM OF ACTION







Reduces fibroid size

Induces apoptosis

Stops Uterine Bleeding

Brings reversible change in endometrial tissue

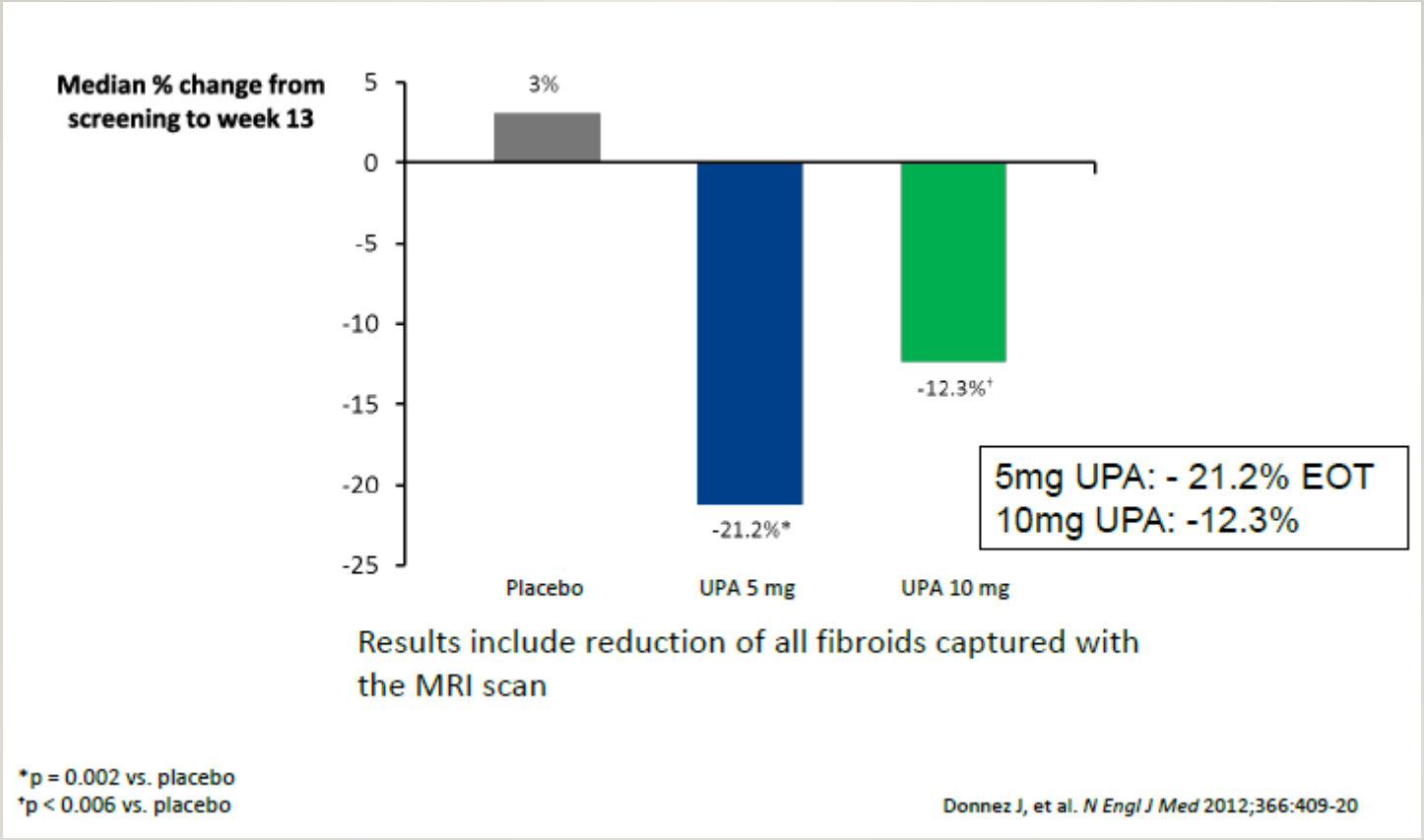
Induces amenorrhea by inhibiting ovulation

STUDIES

- **Ulipristal Acetate Clinical Data: PEARL I and II Clinical Studies**
- **PEARL I:UPA Vs Placebo for Fibroid treatment before surgery**
- **PEARL II:UPA Vs Leoprolide acetate for uterine fibroids**
- **PEARL III: Long term safety study of UPA**

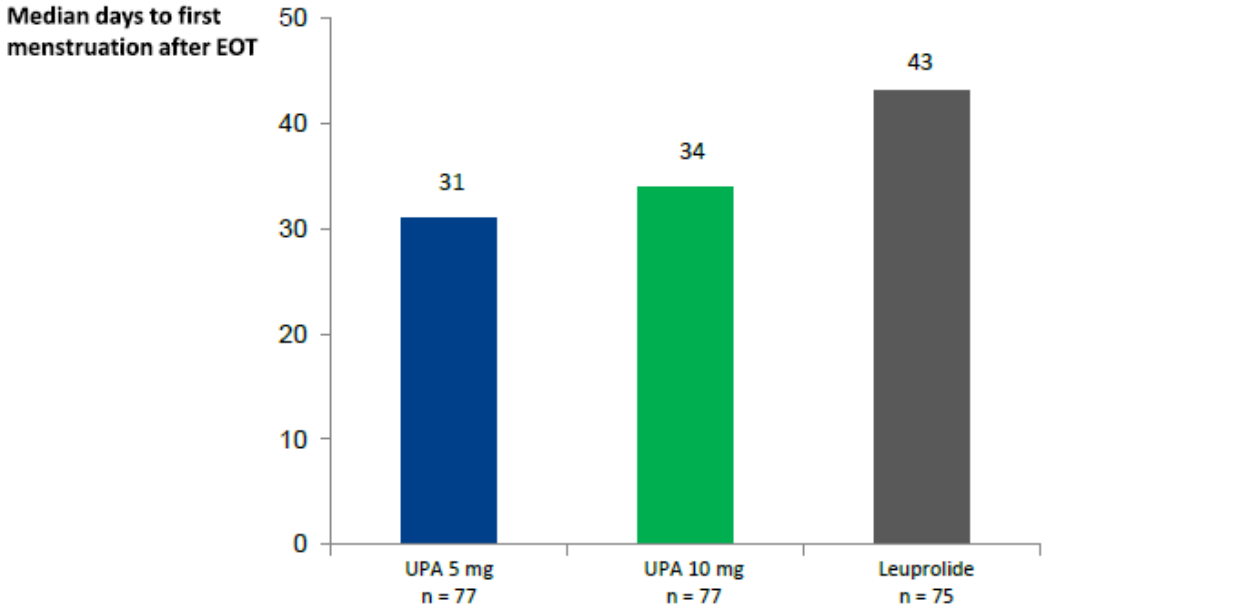
PEARL: Performance Evaluation & Reporting Logic

PEARL I: EFFECT ON FIBROID VOLUME AT END OF TREATMENT



Reduction in size of fibroids by 21 % was achieved at EOT

PEARL II :EFFECT ON MENSTRUAL CYCLE



- EOT for leuprolide is considered to occur 28 days after the last monthly injection
- EOT for UPA is considered to occur at the last day of treatment (week 13)

Donnez J, et al. *N Engl J Med* 2012;366:421-32

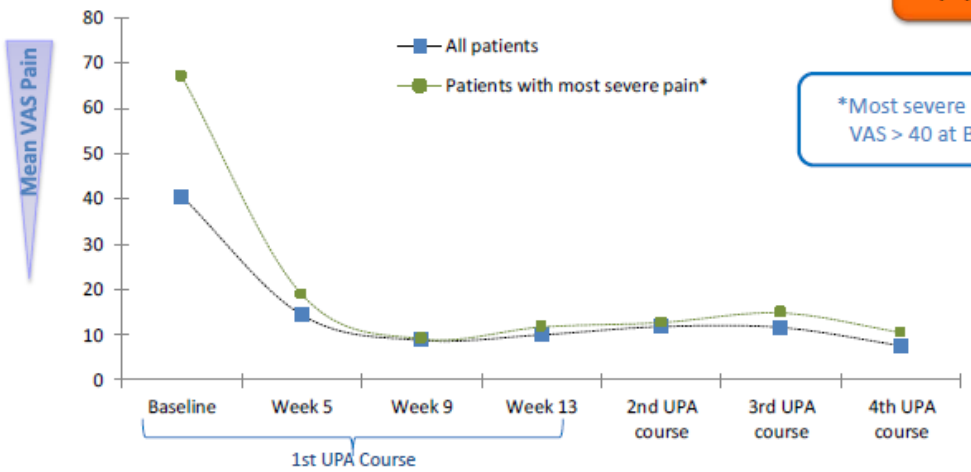
Patients returned to normal menstrual cycle within 4 weeks of end of treatment

PEARL III: IMPACT ON PAIN SCORE

PEARL III & Extension: Effect of UPA 10 mg on Pain (Visual Analogue Scale)

- Degree of pain reduction of 7 points is comparable to reduction of postoperative pain (15) obtained with narcotic and non-narcotic analgesics (9)

ITT population



*Most severe patients: VAS > 40 at Baseline

UPA, ulipristal acetate

Donnez et al, Fertility and Sterility, 2014

7 Point reduction in pain score was observed in intend to treat patients

LITERATURE REVIEW

- 1. A review on the Uterine Fibroid; By Akinyemi BO1, Adewoye BR, Fakoya TA; 004 Oct-Dec;13(4):318-29.
- 2. Review of the Clinical Presentation of Uterine Fibroid and the Effect of Therapeutic Intervention on Fertility; By Atombosoba. A. Ekine1, Lucky O. Lawani2,, Chukwuemeka A. Iyoke3, Israel Jeremiah1, Isa. A. Ibrahim1, 2012-332.
- 3. Fibroids and infertility: an updated systematic review of the evidence; By Elizabeth A. Pritts, M.D.,a William H. Parker, M.D.,b and David L. Olive, M.D.a; 2002.

RESEARCH OBJECTIVE

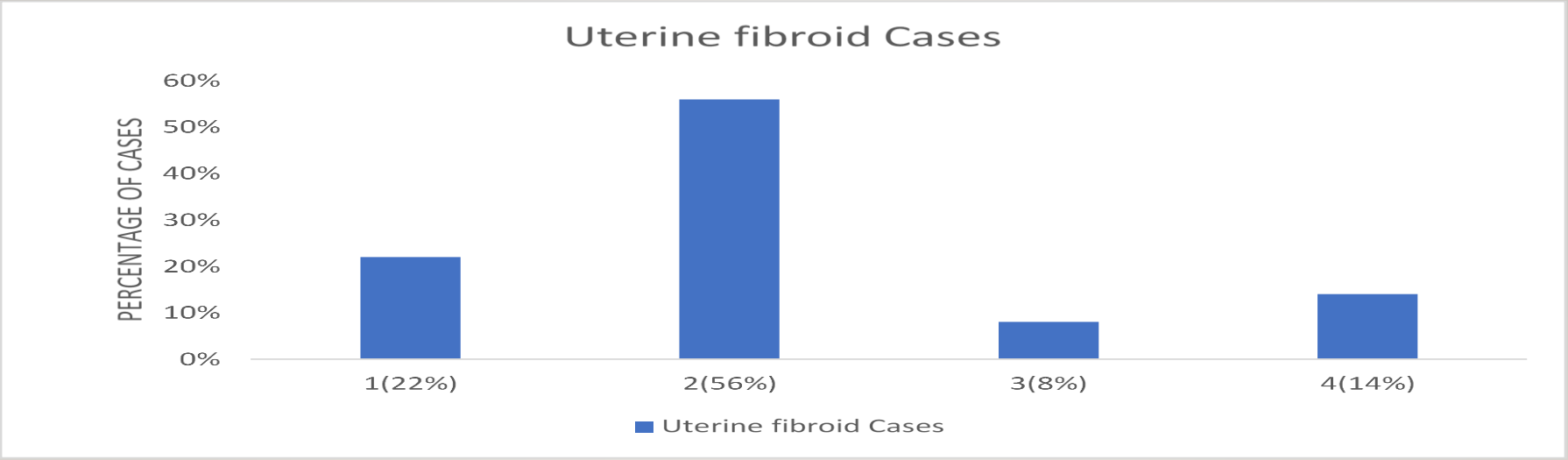
- To understand the current available treatment for uterine fibroids and analyse the gap between them.
- To analyse the market trend, competitors, prescription trend.
- To analyse the positioning of new brand launch.

RESEARCH METHODOLOGY

SR.NO	PARAMETERS	DESCRIPTION
1.	Research Type	Qualitative
2.	Data Collection	Primary and Secondary
3.	Measurement Technique	Structured questionnaire, articles, literature review.
4.	Geographical location	Mumbai
5.	Sample size	38
6.	Sample unit	Gynaecologists
7.	Sampling technique	Random sampling
8.	Analysis technique	MS-Excel

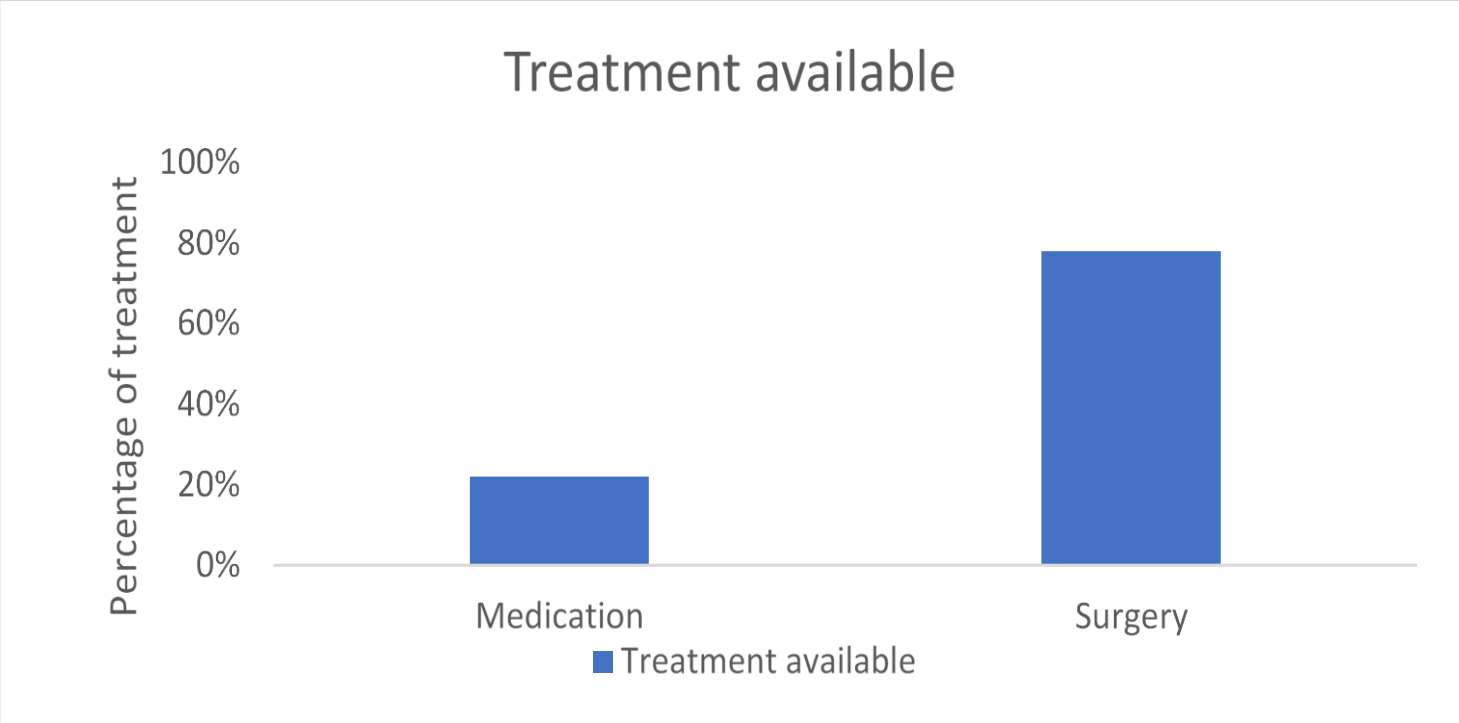
DATA ANALYSIS

1. Total number of patients you treat for Uterine fibroids in a month.



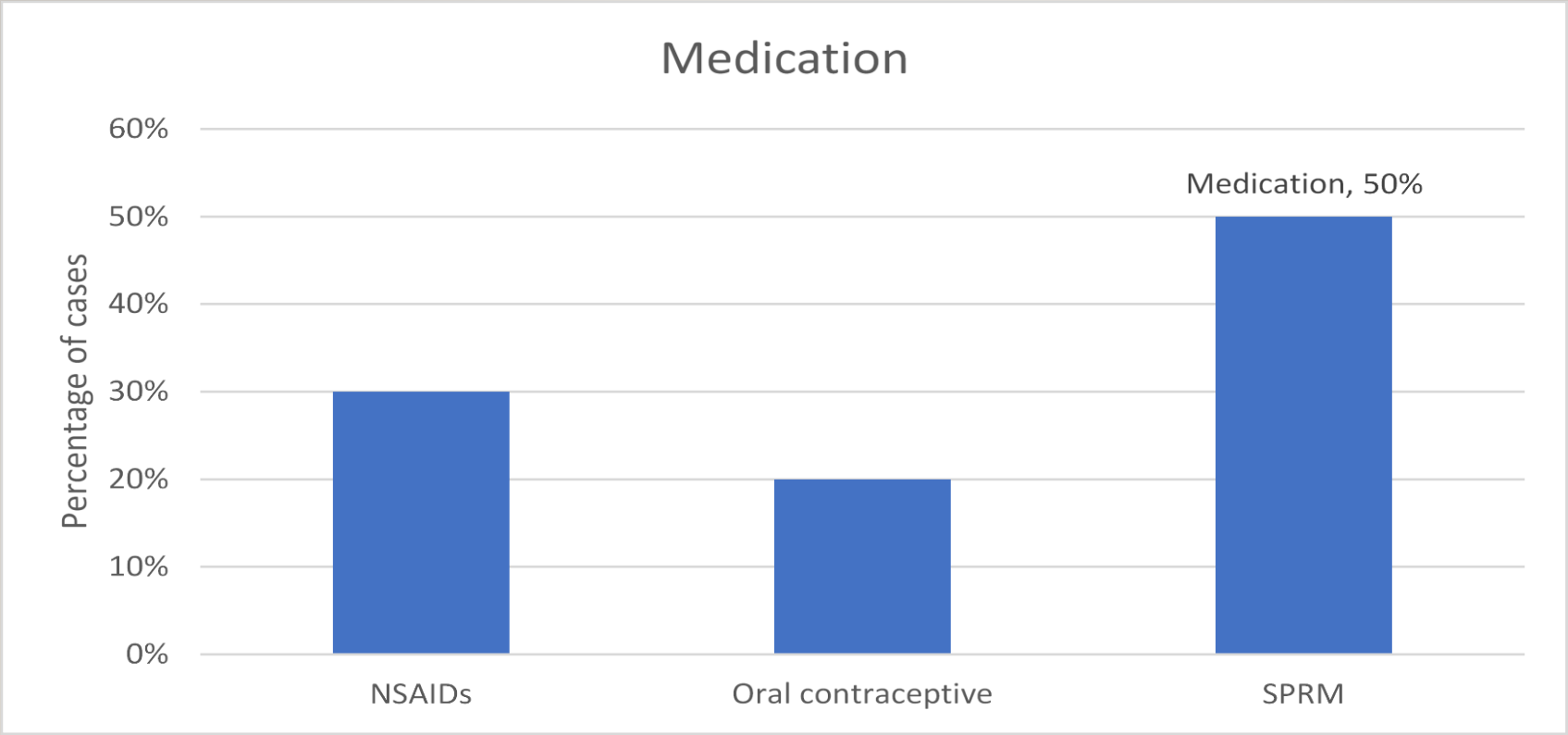
Inference: 100% of the Gynaecologists were aware about Uterine fibroids and -+its complications related with it.56% of them said that they diagnose 2 patient in the month. Majority of them said that they diagnose 2 patients in a month.

1. Current treatment available for Uterine fibroids.



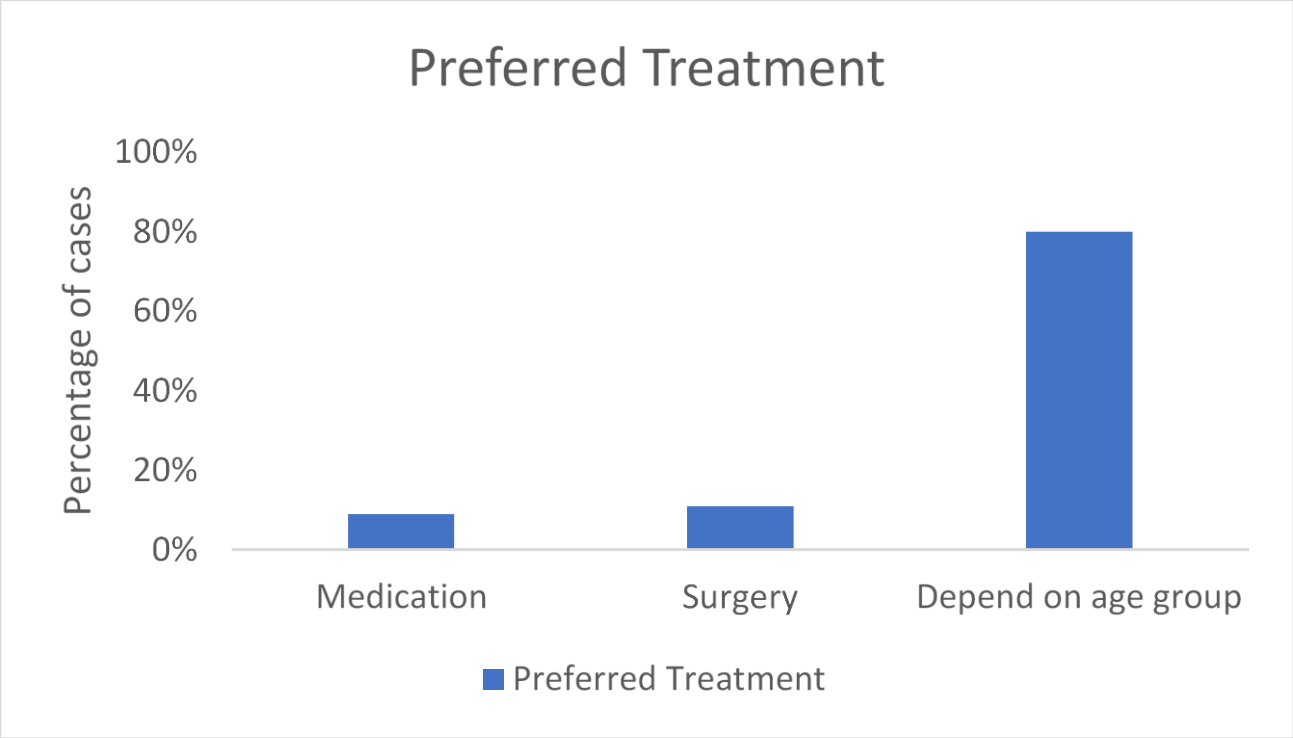
Inference: 78% of the patient prefer surgery while 22% prefer medication for Uterine fibroids. (According to Gynaecologists)

1. Medication prescribed to patients for Uterine Fibroids.



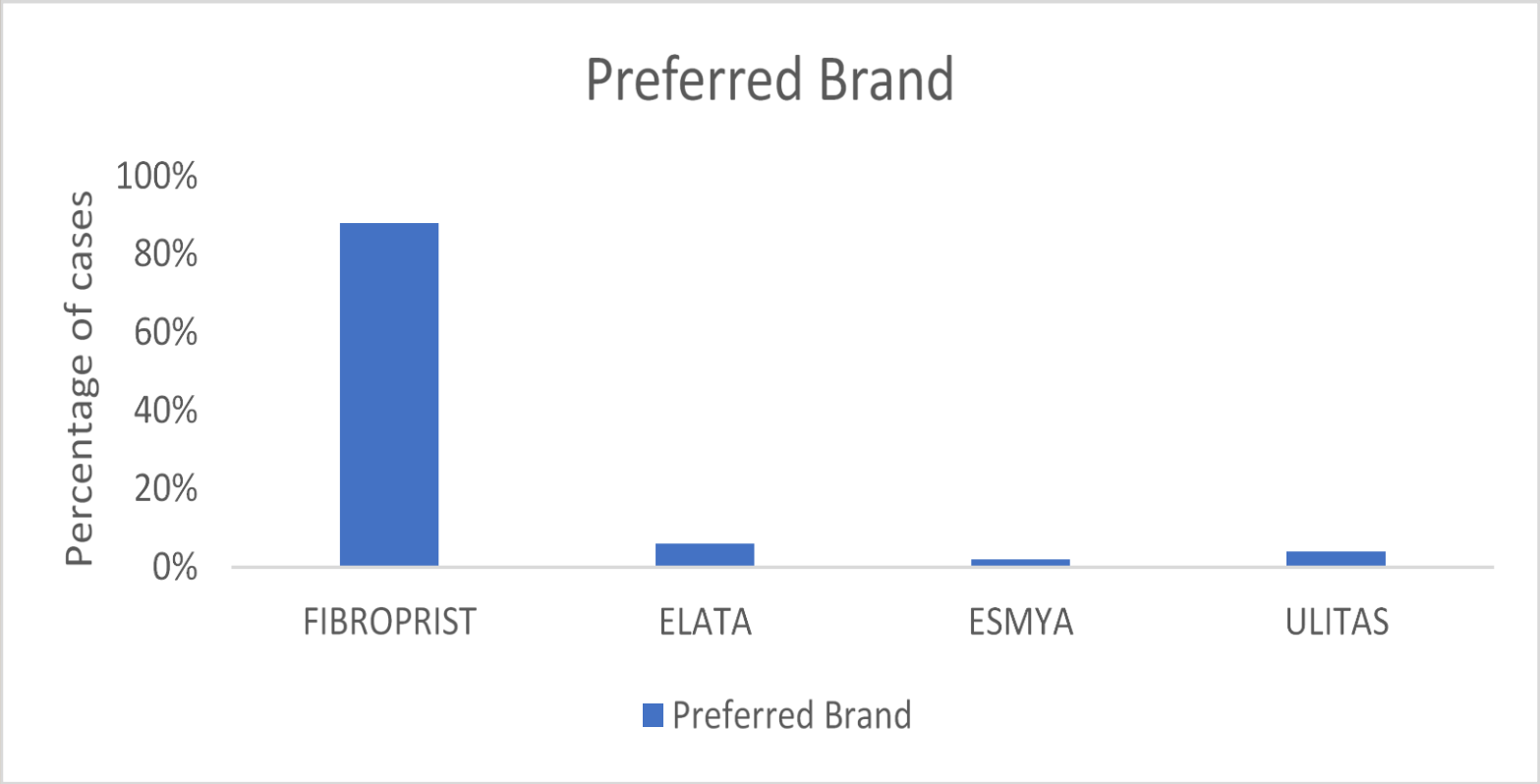
Inference: 50 % of Doctors prescribe SPRM, 30% prescribe NSAID and 20% prescribe Oral contraceptive for treatment of Uterine Fibroids.

1. Most Preferred Treatment for Uterine fibroids.



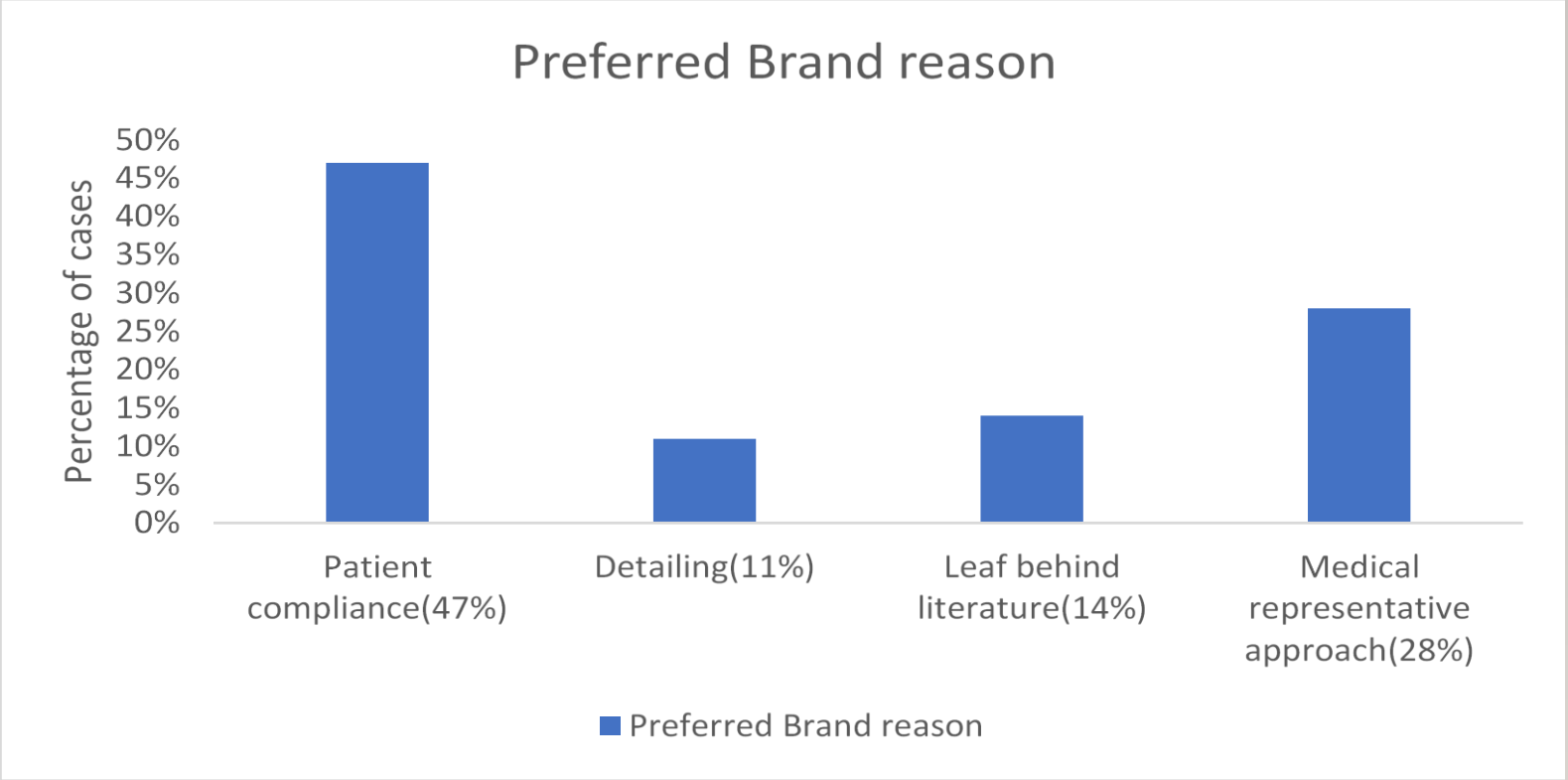
Inference: 80% of Doctor prefer treatment that depends on the age group of patients, 11% said that they prefer surgery in any case while 9% said that they prefer medication.

1. Most Preferred Brand prescribed by Gynaecologists for Uterine Fibroids.



Inference: Fibroprist is the most preferred brand followed by Elata, Esmya and Ulitas.

1. Reason for Preferred Brand.

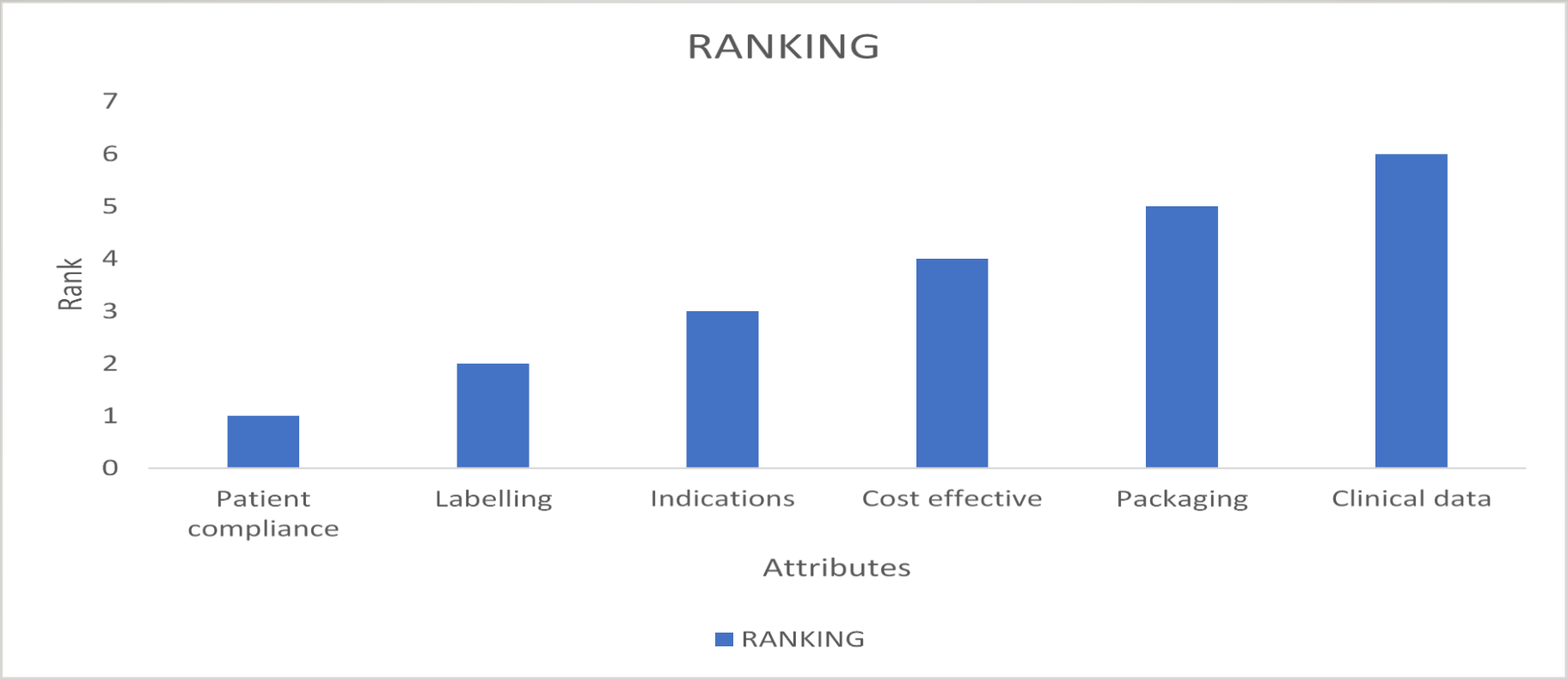


Inferences: According to gynaecologists, patient compliance is an important factor while selecting a particular brand followed by medical representative approach, Detailing as well as leaf behind literature.

1. What are the signs and symptoms noticed for Uterine fibroids?

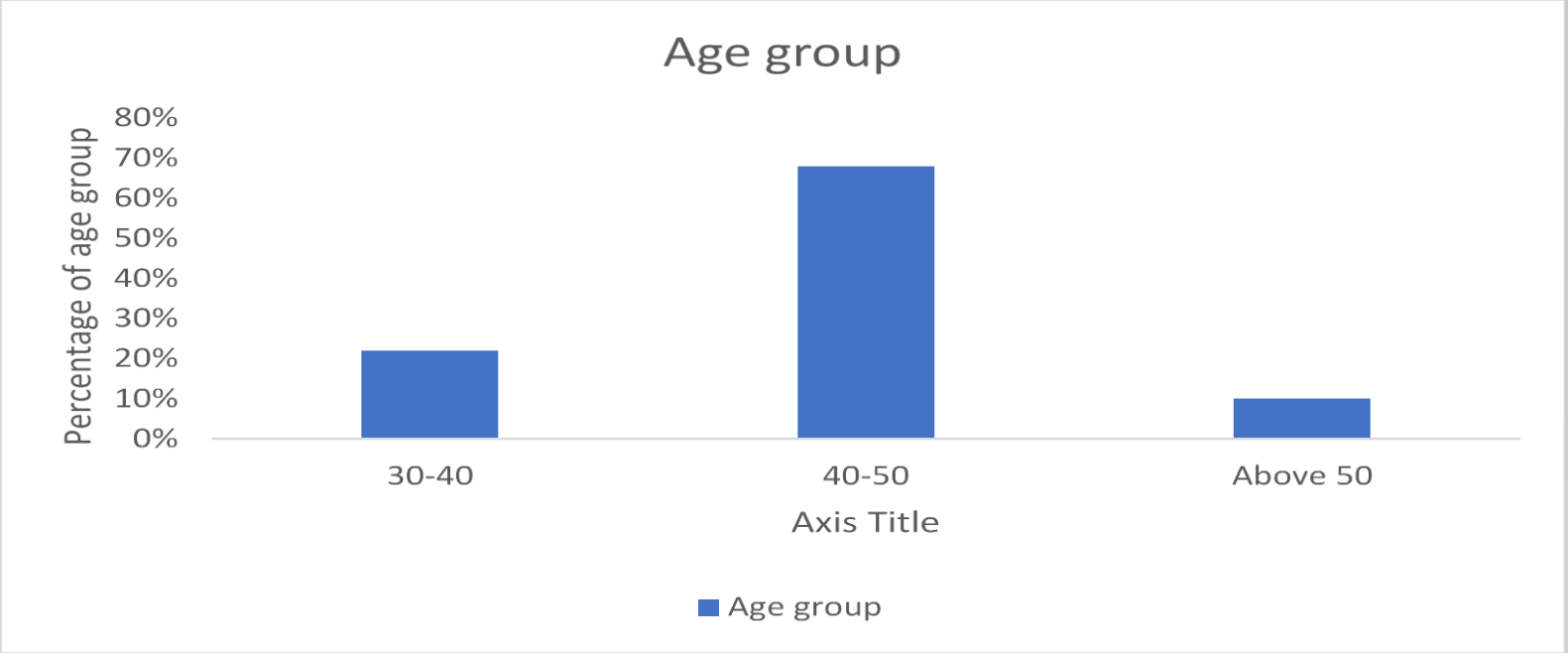
- Menorrhagia
- Dysmenorrhoea
- Anaemia
- Abdominopelvic Pain
- Infertility
- Urinary Pressure symptoms.

1. Important factors you noticed while prescribing a particular brand for uterine fibroids. Kindly rank.



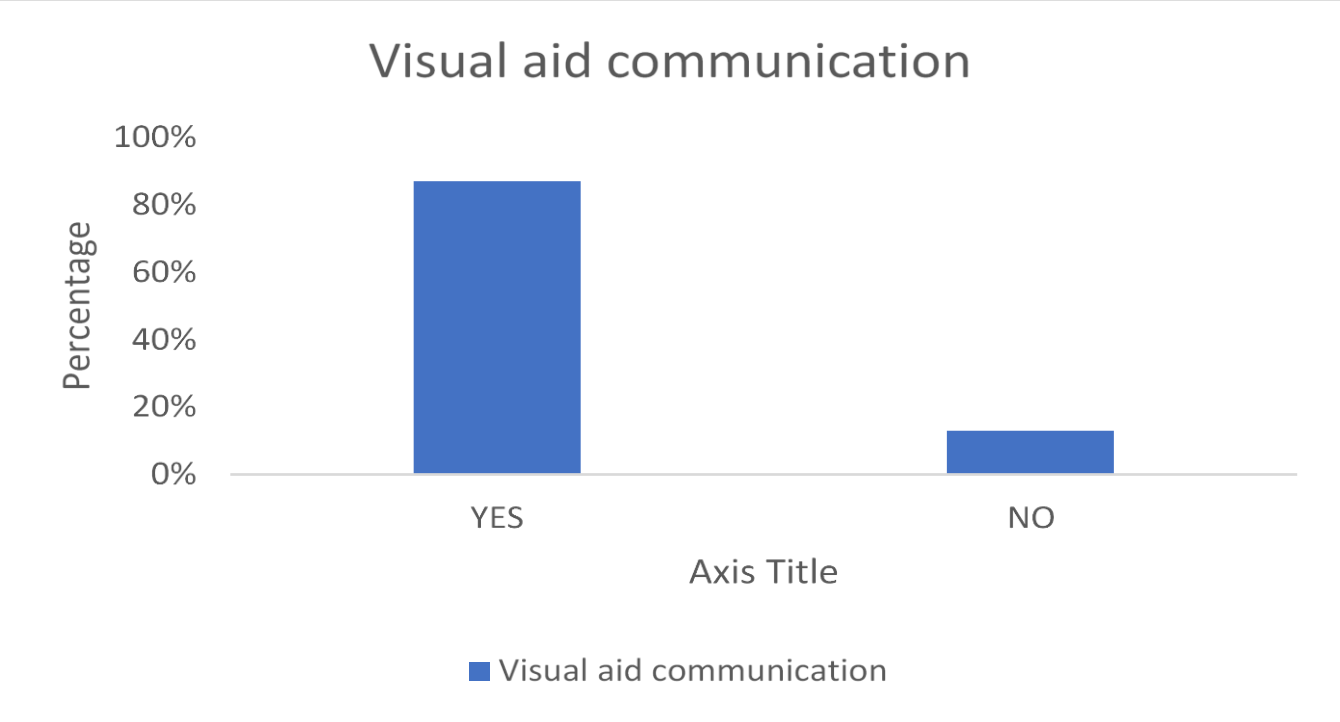
Inferences: Most of the gynaecologists has given first rank to patient compliance followed by labelling, indications, cost effective, packaging and clinical data. Most of them told that clinical data should have valid reference point. These are the points important for a new brand launch.

1. Major age group suffered by Uterine fibroids.



Inference: Major age group that is affected by Uterine fibroids is between 40-50 years of age group.

1. Satisfied with visual aid communication.



Inference: 88% of the Doctors are satisfied by visual aid communication. They were satisfied with the information given in the visual aid related to brand.

Presenting

ULITOP®

Ulipristal Acetate 5 mg Tablets

LIFE ON TOP

The **1st & only medication** indicated for the treatment of Uterine fibroids &
alternative to **Hysterectomy** in adult women of reproductive age

OPPORTUNITY

- ✓ Medical Advantage over surgery
- ✓ Meets unmet need in market
- ✓ Less Number of Players
- ✓ Only oral treatment approved for

  Uterine fibroids
- ✓ Safe & affordable option of Surgery

Rx Duration	Avg. 3 Months
Dosage	OD
Adherence	High
1 Rx =	10 strips
Rx Value =	Rs 15000/-

PRESCRIPTION TREND

According to **SMSRC** Data

SPECIALITY_OVERALL	SPR Rxer%	ULIPRISTAL ACETATE	FIBROPRIST TAB [AKUMENTIS HC]
GYNAE	9.5	100.0	100.0

Inference: Ulipristal acetate is prescribed primarily by Gynaecologists. **Fibroprist (Akumentis)** is the top brand prescribed by most Doctors. This segment occupies **9.5%** of the total shared market.

According to AWACS data.

KEY FINDINGS

It was observed that:

- 1. 100% of the Gynaecologists were aware about Uterine fibroids and its complications related with it.22% of them said that they diagnose 1 patient in the month. Majority of them said that they diagnose 2 patients in a month.
- 2. 78% of the patient prefer surgery while 22% prefer medication for Uterine fibroids. (According to Gynaecologists)
- 3. 50 % of Doctors prescribe SPRM, 30% prescribe NSAID and 20% prescribe Oral contraceptive for treatment of Uterine Fibroids.
- 4. 80% of Doctor prefer treatment that depends on the age group of patients, 11% said that they prefer surgery in any case while 9% said that they prefer medication.
- 5. Fibroprist is the most preferred brand followed by Elata, Esmya and Ulitas.
- 6. According to gynaecologists, patient compliance is an important factor while selecting a particular brand followed by medical representative approach, Detailing as well as leaf behind literature.
- 7. Most of the gynaecologists has given first rank to patient compliance followed by labelling, indications, cost effective, packaging and clinical data. Most of them told that clinical data should have valid reference point. These are the points important for a new brand launch.
- 8. 88% of the Doctors are satisfied by visual aid communication. They were satisfied with the information given in the visual aid related to brand.

CONCLUSION

- Ulipristal acetate has been shown to induce amenorrhoea rapidly in women with uterine fibroids, and it can be a useful treatment in the emergency management of fibroid related acute abnormal uterine bleeding.
- A detailed study related with uterine fibroids was done using secondary research.
- Primary study is conducted in which the structured questionnaire was filled by the gynaecologists of Mumbai region.
- Responses and feedback were noticed by the gynaecologists and data was analysed. By this analysis, we understood the current available treatment and gap between them.
- ULITOP is proved to be an emerging and effective brand for Uterine fibroids.
- Ulitop is launched with distinctive features that is proved clinically.

DelCure

Presenting

1st oral **once daily** therapy for the preoperative treatment of **Uterine Fibroids** for women of **reproductive age**

ULITOP™

Ulipristal Acetate 5 mg Tablets

LIFE ON TOP

RECOMMENDED BY

THE SOCIETY OF OBSTETRICIANS AND GYNAECOLOGISTS OF CANADA

SPRMs in Gynecology: Claude-A. Fortin md Asst .Prof Ob-Gyn McGill University Montreal

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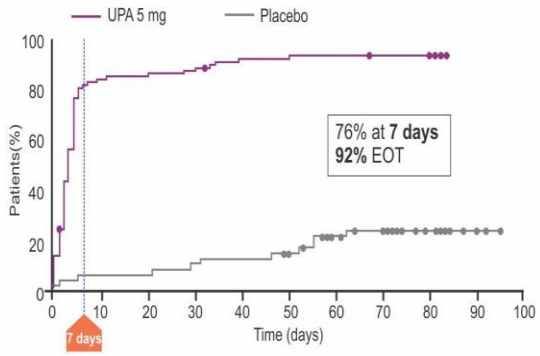
PEARL I

Time to Control of Bleeding in Patients with PBAC < 75



Significantly reduces excessive bleeding

- Fast onset of efficacy
- Controls excessive bleeding within **7 days** of initiation of treatment
- **92%** of patients reported control of bleeding by end of therapy

SPRMs in Gynecology: Claude-A. Fortin md Asst .Prof Ob-Gyn McGill University Montreal
PBAC –Pictorial blood loss assessment chart
EOT-End of treatment,
UPA : Ulipristal Acetate

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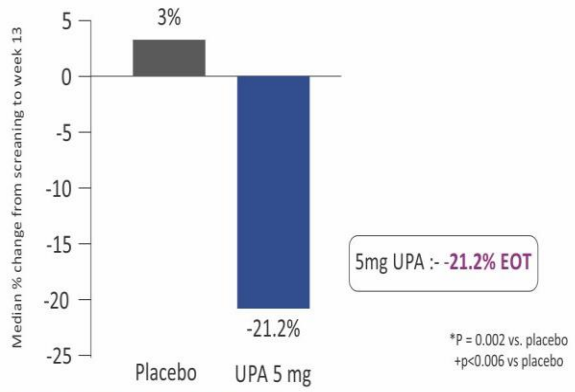
PEARL II

Effect on fibroid volume (MRI) (Ultrasound) at End of Treatment



Demonstrated reduction & Maintainence of Fibroid Volume

- Reduced size of fibroid by 21% from baseline in PEARL I
- Reduces median fibroid **volume by 36%** at week 13 in PEARL II
- Maintains fibroid reduction for 6 months post treatment in patients who did not have a hysterectomy

SPRMs in Gynecology: Claude-A. Fortin md Asst .Prof Ob-Gyn McGill University Montreal
PEARL: Performance Evaluation and Reporting Logic,
UPA : Ulipristal Acetate


Happy Selling