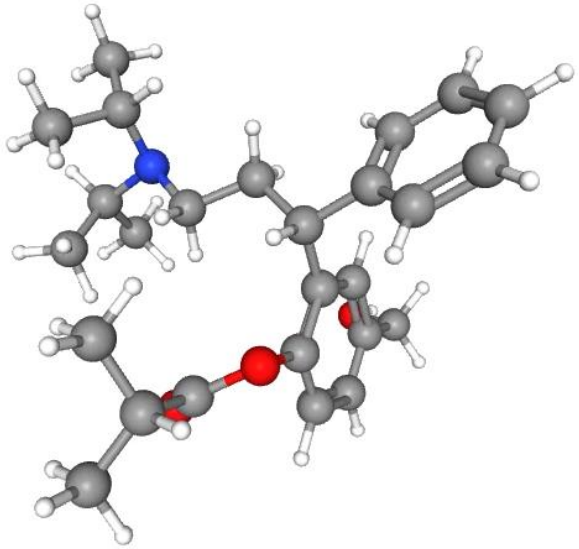


GO TO MARKETING STRATEGIES OF FESOBIG

Best in Class for Incontinence Control

AYUSHI SINGH
0296
MBA PM 13

Overactive Bladder

- Overactive bladder (OAB) is a common condition that is defined as “urinary urgency, usually accompanied by frequency and nocturia, with or without urge urinary incontinence” by the International Continence Society .
- The term, developed by the International Continence Society, is suggestive of underlying detrusor overactivity, but may be related to other forms of urethrovesical dysfunction.
- OAB is a chronic condition that has a significant impact on health- related quality of life and may require life-long treatment.

Research and Reports in Urology 2016:8 113–122

Prevalence

More Than

400 million

People suffer from UI worldwide

50 million People suffer from UI in India

1 in 3 women

1 in 8 men

experience Incontinence

10%-30%

younger than 65

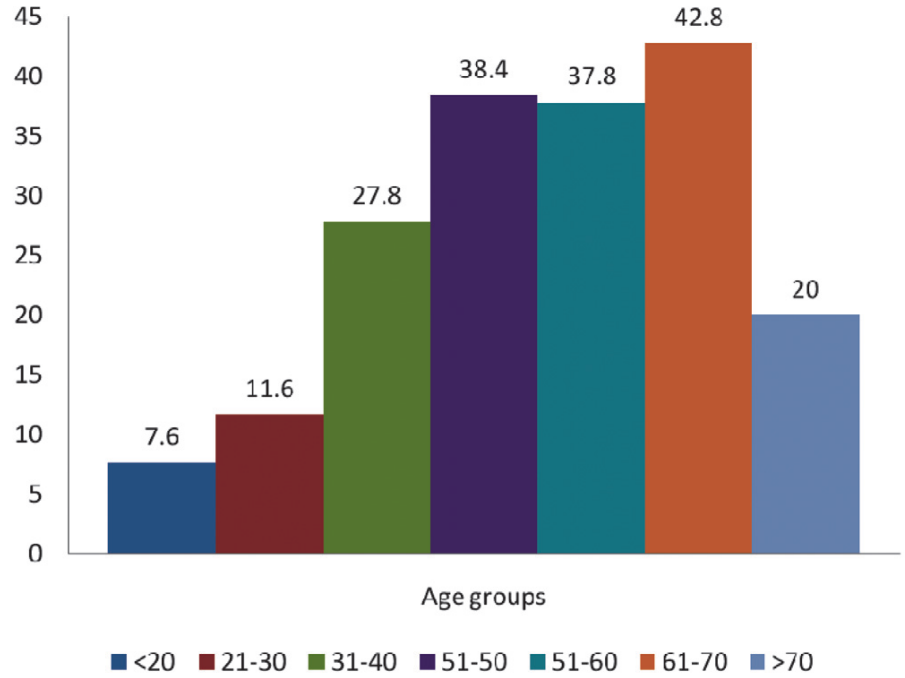
65+ years old

30%-55%

http://physiocentre.in/urinary-incontinence/

Prevalence

- Numerous countries have reported that the prevalence of UI ranged from approximately 5% to 70%.
- Women are more prone to the condition than men UI in females ranges between 10% and 58%
- Women in India have also been reported to have high because of shyness, fear of surgery, dependency on husband.



Age wise (years) distribution of urinary incontinence (%)

Indian J Urol. 2013 Jan-Mar; 29(1): 31–36.

Impact of Urinary Incontinence on Quality of Life

Physical

- Limitations or cessation of physical activities

Sexual

- Avoidance of sexual contact and intimacy

Psychological

- Guilt/depression
- Loss of self-respect and dignity
- Fear of:
  - being a burden
  - lack of bladder control
  - urine odor
- Apathy/denial

Occupational

- Absence from work
- Decreased productivity

Quality of Life

Social

- Reduction in social interaction
- Alteration of travel plans
- Increased risk of institutionalization of frail older persons

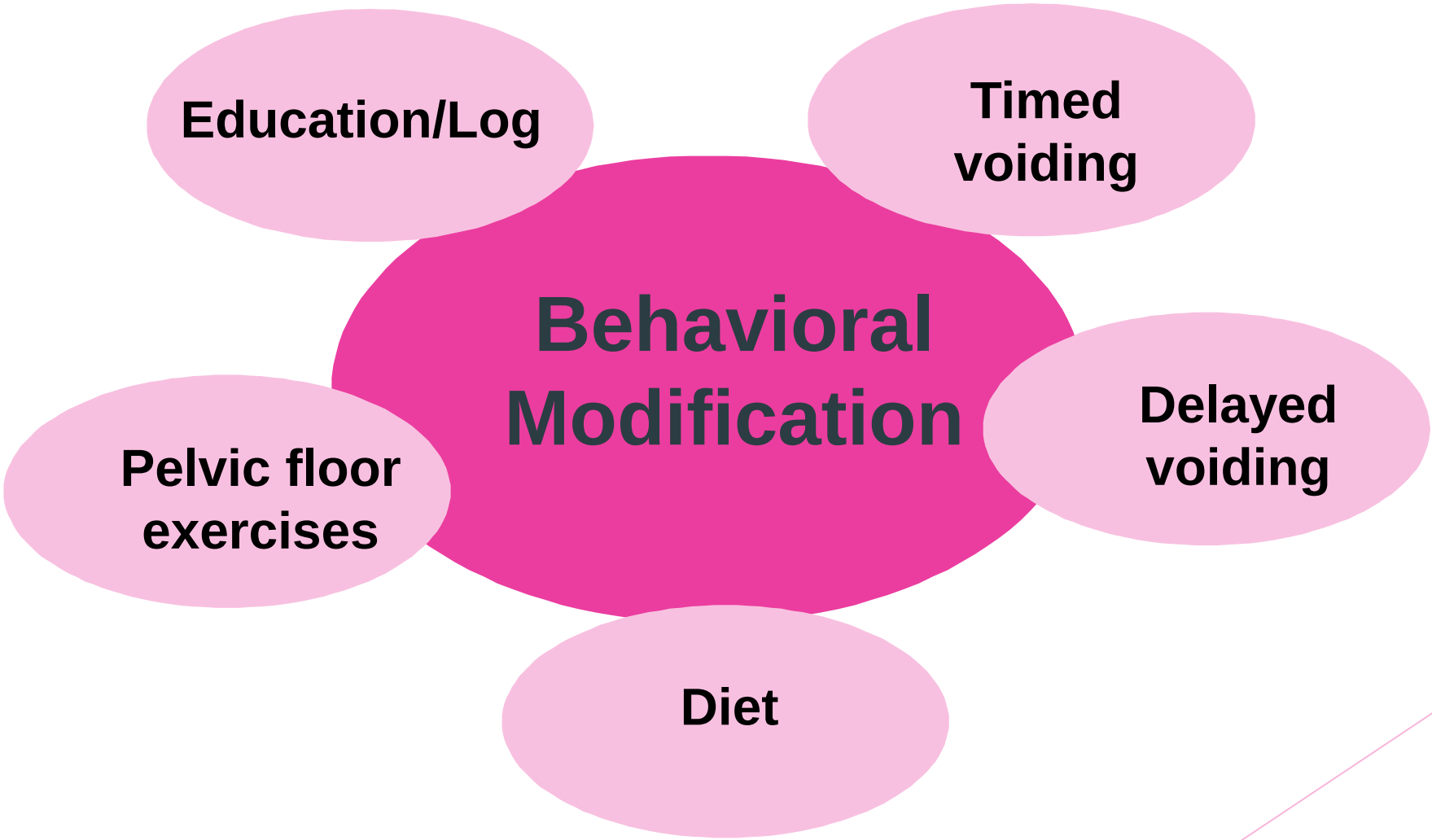
Domestic

- Requirements for specialized underwear, bedding
- Special precautions with clothing

Education

- Clinicians should provide education to patients regarding normal lower urinary tract function, what is known about OAB.
- The benefits versus risks/burdens of the available treatment alternatives and the fact that acceptable symptom control may require trials of multiple therapeutic options before it is achieved.
- So the treatment demands patience and motivation for long-term improvements.

Behavioral Modification



Pharmacologic Therapy for the Treatment of OAB

- The newer anticholinergics are more selective for the M2 and M3 receptor subtypes and were developed increased selectivity would improve efficacy and reduce side-effects.
- Normal ageing is associated with changes to the blood–brain barrier, with increased permeability to inflammatory mediators and drugs.
- There is evidence that the newer and more M2/M3-specific antimuscarinics have little or no impact on cognition, with cognitive safety data available for darifenacin, solifenacin and Fesoterodine.

Use of Antimuscarinics in OAB

- Acetylcholine is the primary contractile neurotransmitter
- Antimuscarinics are the pharmacological mainstay of treatment
- Act by inhibiting the binding of Ach to M2 and M3 receptors on detrusor smooth muscle cells and other structures within bladder wall
- There are six antimuscarinic agents available for the treatment of OAB worldwide: oxybutynin, tolterodine, fesoterodine, trospium, darifenacin, and solifenacin
- Are generally well-tolerated except for some adverse effects like dry mouth, constipation, headache and blurred vision

Therapeutics and Clinical Risk Management 2009:5 869–876

Ideal Muscarinic Receptor Antagonist

Efficacious

- inhibits involuntary bladder contractions
- does not adversely affect volitional detrusor activity

Organ selective

- preferentially affects the bladder over other organs
- results in minimal side effects and improved tolerability

Durable effects

- improves compliance and/or persistency

Provides clinical effectiveness

- the optimal balance of efficacy, tolerability, and compliance/persistency

Fesoterodine

- Fesoterodine is a unique competitive muscarinic receptor antagonist.
- After oral administration, Fesoterodine is rapidly and extensively hydrolyzed by nonspecific esterase's to its active metabolite, 5-hydroxymethyl tolterodine (5-HMT), which is responsible for the anti-muscarinic activity of Fesoterodine.
- The conversion of Fesoterodine fumarate extended-release tablet to its active metabolite is not dependent on cytochrome P450 enzymes

Therapeutics and Clinical Risk Management 2009:5 869–876
https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/022030lbl.pdf

Fesoterodine - Mode of Action

- Fesoterodine is a competitive muscarinic receptor antagonist
- Muscarinic receptors play a role in contractions of urinary bladder smooth muscle
- Inhibition of these receptors in the bladder is presumed to be the mechanism by which Fesoterodine produces its effects
- Administration of Fesoterodine increased the volume at first detrusor contraction and bladder capacity in a dose-dependent manner.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/022030lbl.pdf

Fesoterodine: AEs

- Gastrointestinal: Dry mouth, constipation, dyspepsia, nausea, abdominal pain
- Infections: UTI, URTI
- Eye disorders: dry eyes
- Renal and Urinary: Dysuria, retention
- Others: Myalgia, insomnia, ALT/GGT increase, skin rash

https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/022030lbl.pdf

OAB in elderly

- The OAB symptom complex is increasingly prevalent in association with increasing age.
- In choosing antimuscarinic therapy, cognitive functions of patients should be taken in to consideration for elderly patients.
- Conservative and lifestyle measures sometimes may effective in older people.
- Elderly people may require higher doses of medication.
- Due to potential CNS adverse effects of anticholinergic agents, increased cognitive burden

Fesoterodine in Elderly

Antimuscarinics	FORTA Class		Antimuscarinics	FORTA Class
Fesoterodine	**B**		Darifenacin	C
Solifenacin	C		Tolterodine	C
Trospium	C		Propiverine	D
Oxybutynin	D			
β3-agonist	**C**		**Mirabegron**	

- Rating of Antimuscarinics on the LUTS-FORTA (Fit For The Aged) classification, which classifies appropriateness of oral drugs for long-term treatment of LUTS in older patients -
- **A (Absolutely), B (Beneficial), C (Careful), D (Don't)**

Research and Reports in Urology 2017:9 209-218

Fesoterodine higher affinity for M2 & M3 receptors

- The efficacy and safety profiles of different antimuscarinic drugs depend on their interactions with muscarinic receptors that are widely distributed throughout the body.
- Fesoterodine binds onto muscarinic receptors on both the detrusor and bladder mucosa. ***5-HMT has ten-times more affinity for muscarinic receptors***

Clin. Invest. (2012) 2(8), 825-833

Flexible dose Fesoterodine significantly improved OAB

- Dose flexibility offers the advantage of an individually tailored treatment to achieve the optimum balance between efficacy and adverse events.
- A strategy based on patient-requested dose increases has been found to consistently improve overactive bladder symptoms.
- Selecting a drug which offers dose flexibility seams a reasonable first-line treatment approach.

Int J Clin Pract. 2009 Apr;63(4):560-7.

Comparisons of Fesoterodine with Antimuscarinic drugs & β3-adrenoceptor agonist

Paramaters	Solifenacin	Tolterodine	Mirabegron	Fesoterodine	Outcome
Selectivity	M1, M3	M2, M3	beta-3 receptor	M2, M3	Balanced M2-M3 affinity, results in contraction control and relaxation.
FORTA Class	C	C	C	B	Safe & effective in elderly
Metabolism	Mediated by cytochrome P450 enzyme	Mediated by cytochrome P450 enzyme	Mediated by cytochrome P450 enzyme	Bypasses hepatic cytochrome pathway	Predictable dose-response
Ability to cross BBB	Moderate	Moderate	Low	Low	No cognitive side effects
Tolerability	Low	Moderate	Moderate	Moderate	Lesser treatment discontinuation rate
Discontinuation to treatment	Higher	Lesser	Lesser	Lesser	Improved adherance

BBB: blood brain barrier FORTA: Fit fOR the Aged

Research and Reports in Urology 2017:9 209-218

J Int Med Res. 2021 Sep; 49(9):

Current Medicinal Chemistry, 2009, *16*, 4481-4489

Comparisons Safety Efficacy of Fesoterodine with other Antimuscarinic drugs

Efficacy and Safety

- Fesoterodine demonstrated their efficacy and safety in well-designed, controlled studies conducted during their clinical development.

Treatment Compliance

- Overall, adherence is significantly better for extended release Fesoterodine than immediate release antimuscarinic agents.

Dose Flexibility

- Fesoterodine dose flexibility offers the advantage of an individually tailored treatment to achieve the optimum balance between efficacy and adverse events than other antimuscarinic agents.

Int Braz J Urol. 2021; 47: 1091-107

Adv Urol. 2011;2011:820816.

Fesoterodine: Highlights

- Safe and effective in elderly patients
- AUA recommended as first pharmacological option after behavioral therapy
- Pharmacological profile is optimal for treatment of OAB
- Better patient satisfaction
- Dose escalation may allow for improved outcomes
- Has a better safety profile
- Less cross BBB, hence less CNS adverse effects
- Fesoterodine is as effective as other antimuscarinics used for OAB

RESEARCH METHODOLOGY

- The opinions, preferences, and practises of gynaecologists in Hyderabad about the use of Fesobig (fesoterodine 4 mg/8 mg pill) for treating overactive bladder (OAM) were surveyed. The survey shown below was used:
- The goals and research questions of the questionnaire were to find out more from the OHC gynaecologists in Hyderabad about the patients' preferred drugs, dose, and duration. Follow Fesobig to learn more about the hiring process in the context of OAB management.
- The viewpoints, preferences, and practises of Hyderabadi gynaecologists towards the management of an overactive bladder
- • Study Design: A questionnaire should be used to collect data on item understanding.

RESEARCH METHODOLOGY

- Sampling strategy:

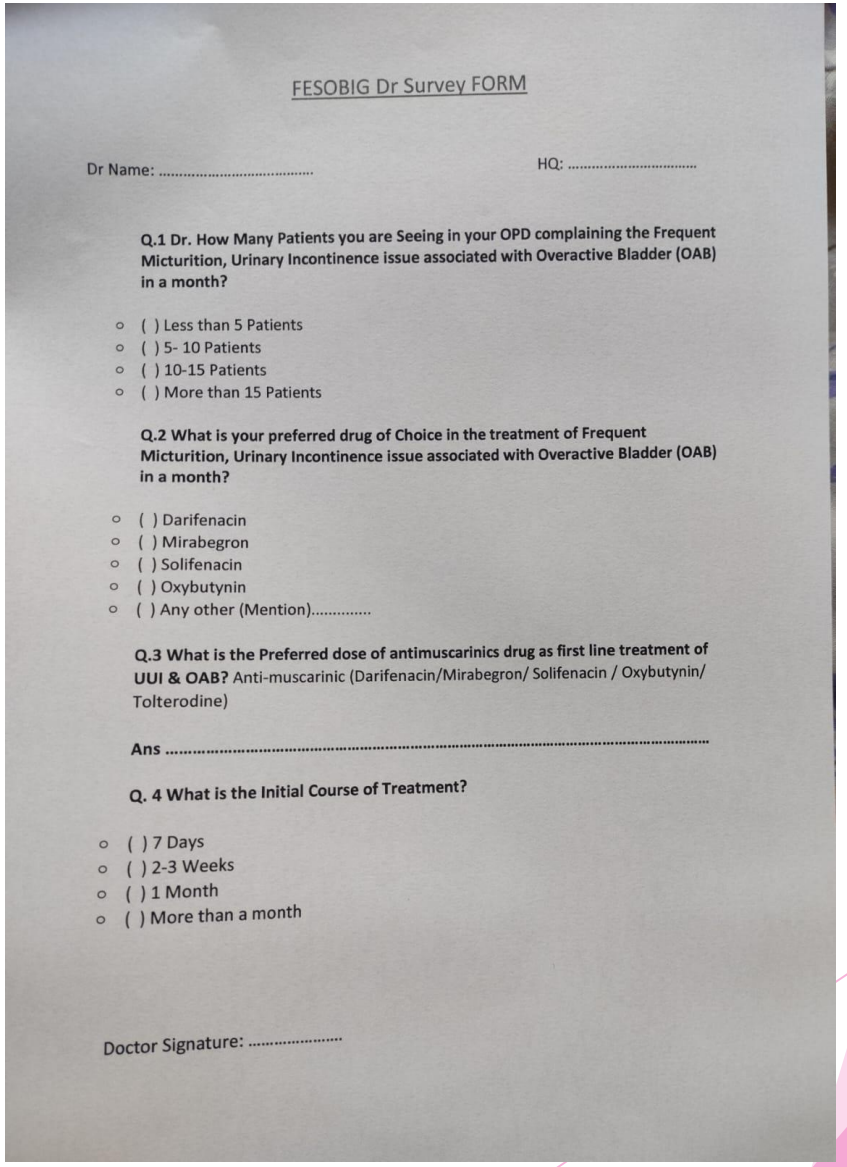
Participants in the study were gynaecologists in Hyderabad.

- I chose a practises after asking local doctors for suggestions.
- Gynaecologists from Hyderabad are letting me take samples from thirty of them. After getting a list of gynaecologists from MSN private practises, use a technique to choose samples.

RESEARCH METHODOLOGY

- Opinions, preferences, and practises of gynaecologists in Hyderabad with relation to the administration of Fesobig (fesoterodine), a medication used to treat overactive bladder (OAM)
- **Tools for integrated search**
- Create search tools that use precise and precise search criteria. This study concentrated on the primary absence of OAB in OAB patients, OAB-related absence within one month, treatment options, and effects of absence-related OAB within one month.
- The main and initial course of treatment for UUI and OAB is antimuscarinic medicine.
- Data collection: This study was conducted for Obstetrician in Hyderabad.
- Make sure answers are private and anonymous to encourage objective and fair responses.
- Data Analysis: Perform a quantitative data analysis based on the type of data collected.

PAPER BASED QUESTIONNAIRE



FESOBIG Dr Survey FORM

Dr Name: ..... HQ: .....

Q.1 Dr. How Many Patients you are Seeing in your OPD complaining the Frequent Micturition, Urinary Incontinence issue associated with Overactive Bladder (OAB) in a month?

- ( ) Less than 5 Patients
- ( ) 5- 10 Patients
- ( ) 10-15 Patients
- ( ) More than 15 Patients

Q.2 What is your preferred drug of Choice in the treatment of Frequent Micturition, Urinary Incontinence issue associated with Overactive Bladder (OAB) in a month?

- ( ) Darifenacin
- ( ) Mirabegron
- ( ) Solifenacin
- ( ) Oxybutynin
- ( ) Any other (Mention).....

Q.3 What is the Preferred dose of antimuscarinics drug as first line treatment of UUI & OAB? Anti-muscarinic (Darifenacin/Mirabegron/ Solifenacin / Oxybutynin/ Tolterodine)

Ans .....

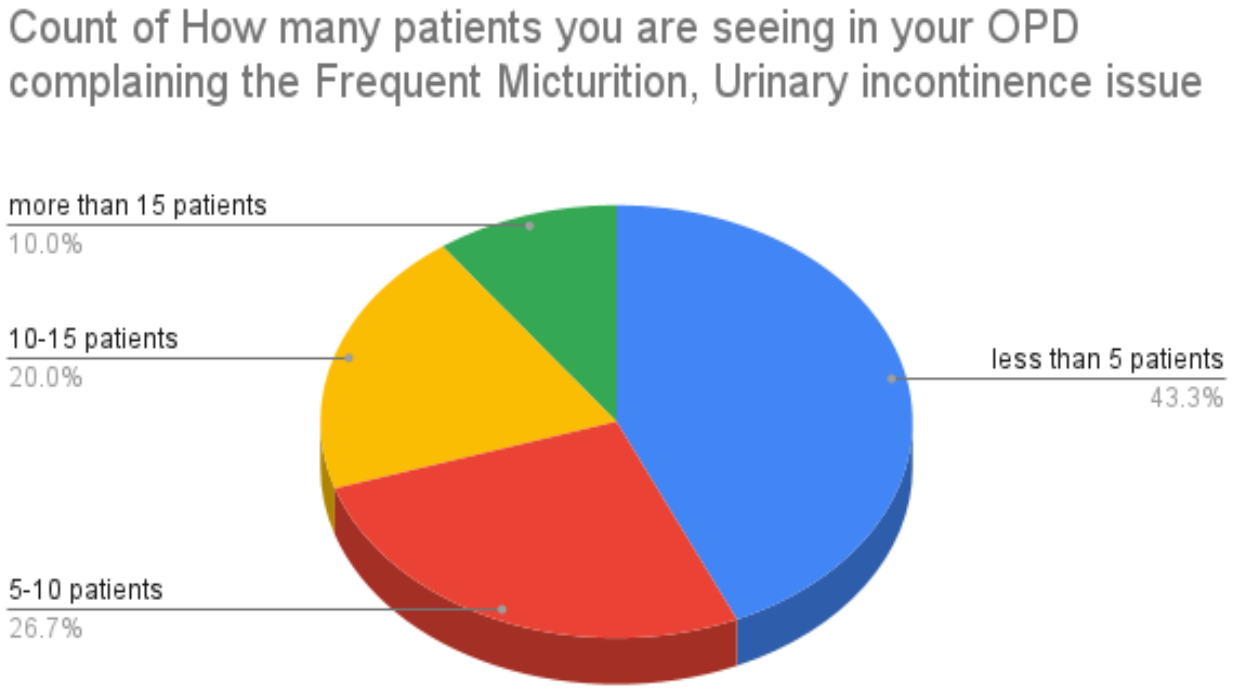
Q. 4 What is the Initial Course of Treatment?

- ( ) 7 Days
- ( ) 2-3 Weeks
- ( ) 1 Month
- ( ) More than a month

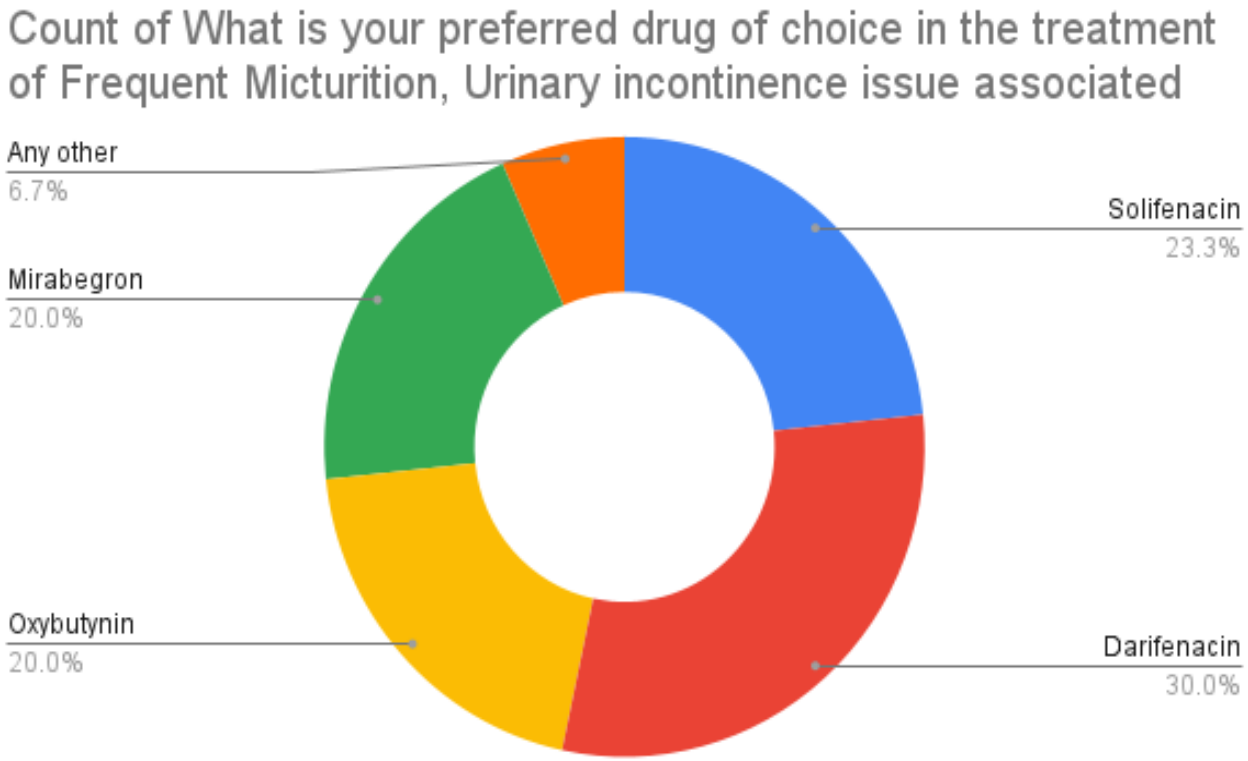
Doctor Signature: .....

RESULTS

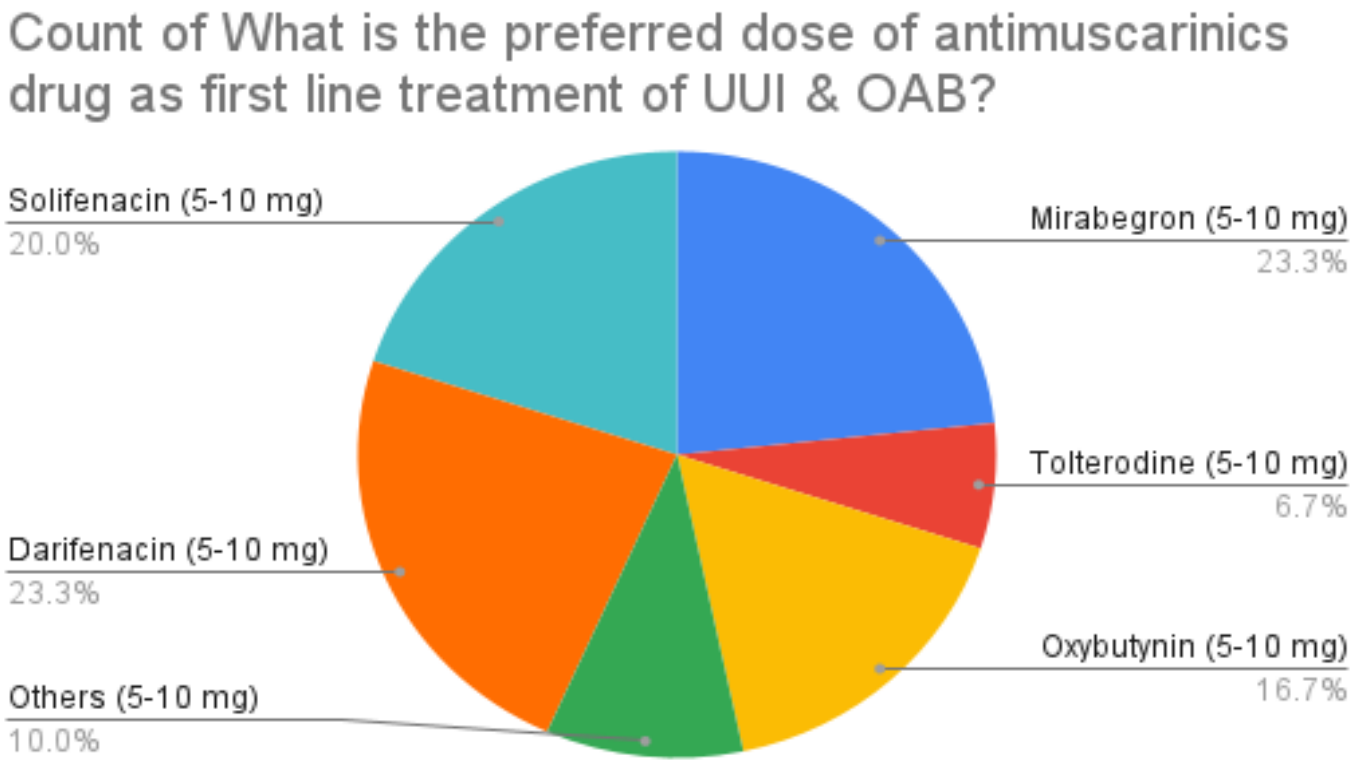
- In Hyderabad, a survey with a sample size of 30 gynaecologists was conducted using the random sampling method. This is directed at Hyderabad's gynaecologists. The number of OAB patients, the drug the doctor preferred, the recommended dose, and the ideal time to provide the medication to the patient were all questions in this poll.



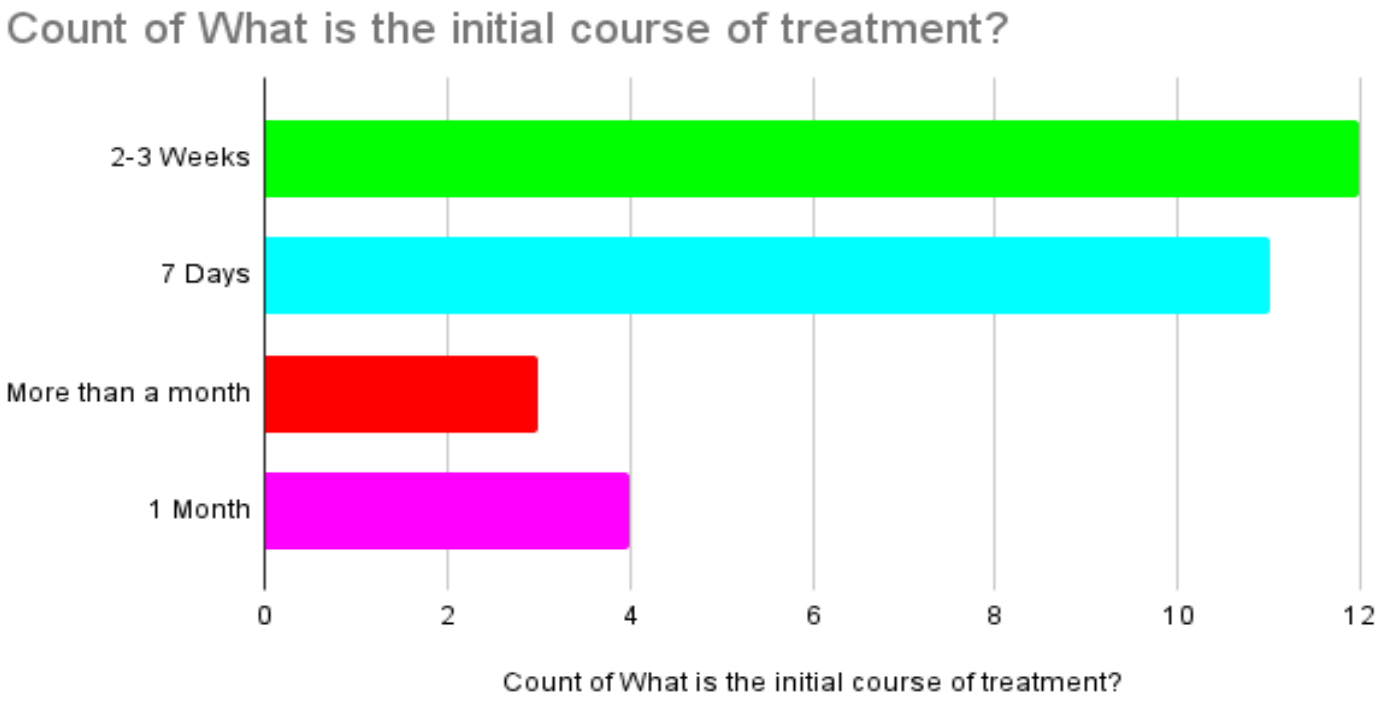
The pie chart here shows patients with frequent urination and urinary incontinence. From this pie chart, we can conclude that less than 5 patients per month have OAB most of the time (43.3%).



Pie chart shows that Darfenacin (30%) is the drug of choice for gynecologists in Hyderabad for frequent urination, urinary incontinence.



This pie chart shows that mirabegron (5-10 mg) and darfenacin (5-10 mg) are the antimuscarinic drugs of choice as first-line therapy for UUI and OAB among Hyderabad gynecologists.



- This bar graph depicts that the duration of 2-3 weeks is the most preferred initial course of treatment by gynecologists in Hyderabad.

KEY FINDINGS

- Based on the findings, it can be concluded that the number of patients suffering from UUI on a monthly basis is very low. Therefore, awareness of OAB needs to be increased so that more women can access education and treatment. Darfenacine and Mirabegron are currently the most popular drugs recommended by gynecologists in Hyderabad. Physicians should be informed about Fesobig and its safety and efficacy for it to be the next drug of choice in the treatment of OAB. The 2-3 week treatment preferred by the gynecologist in patients with UUI is also among the main findings.

CONCLUSION

- Businesses may greatly contribute to the spread of correct and up-to-date knowledge through publications, CME conferences, and educational resources. It is essential for the development of Fesobig as an effective and user-friendly treatment to comprehend the techniques gynaecologists are now using to control OAB. Through publications, CME conferences and instructional materials, businesses can contribute significantly to the dissemination of accurate and current knowledge.


Thank You