Over active bladder: A review of current practices in evaluation and management

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ABSTRACT

Over Active Bladder is one of the commonest urological problem affecting millions of people from both gender worldwide. It has far-reaching consequences on individual quality of life. It is difficult to manage because none of the single treatment modality has been proved effective, although many management options exist. Mostly, a combination of treatment modalities is needed to tackle the symptoms of Over active bladder successfully. The over active bladder is an embarrassing for patients and usually have far reaching effects on mental and physical health. The present review was conducted according to the preferred reporting items for systematic reviews and meta-analyses guidelines. We had provided an overview this pathology in this review with special emphasis on risk factors, recent advances in assessment, diagnosis and different therapeutic options including medical and conservative management. Moreover, the management of refractory OAB, guidelines for specialist clinic referral and available resources for general practitioners and patients. So the main objective of this review is to give important information's to the clinicians regarding the management of Overactive bladder and to improve patients care and counseling in primary care setting. The findings of the current review are expected to be helpful to comprehend the existing literature and challenges and to manage OAB.

Keywords: Overactive bladder, Hematuria, Dysuria, Dyspareunia, Pelvic organ prolapse, Incontinence

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INTRODUCTION

Over Active Bladder (OAB) is defined by International Uro-Gynecological Association (IUGA) and International Continence Society (ICS)/ as "a symptom syndrome of urinary urgency, usually accompanied by frequency and nocturia, with or without urge incontinence, in the absence pathological (e.g. UTI, stones, bladder tumor) or metabolic factors (e.g. diabetes)"[1]. Existing guidelines on OAB has declared that generally it is not a life-threatening medical problem. Therefore, the treatment benefits should be considered carefully against the potential side effects and to decide carefully whether not offering any treatment to the patient is an acceptable option or not[2]. Mostly, the majority of patients usually reports a higher concern about their symptoms and looking for some medical treatment or intervention. Statistically, OAB affects one in every three elderly individual, common in female and costly in treatment. Literature reported that the OAB is prevalent more above 40 years of age and affect almost 36% of male and 43% of female[3].

The effects of OAB on mental and physical wellbeing and life quality of an individual are far-reaching, such as sleep disturbance, fall-associated injuries, breakdown of skin due to incontinence, depression and poor quality of life .It is an embarrassing health problem that interferes with daily life activities as well as impact social functioning[4]. Therefore, following different management approaches used to manage OAB symptoms and improve patient quality of life[5].

Conventionally, the approach in management of OAB is behavioral modification, Pelvic Floor Muscle Training (PFMT), bladder retraining and biofeedback, followed by β3 agonists or antimuscarinic drugs. Any failure in managing this pathology with these approaches i.e., conservative, conventional and pharmacotherapeutic may leads to refractory OAB[4,5]. The different modalities for the management of refractory OAB are neuromodulation (i.e. posterior tibial/sacral afferents), intravesical botulinum toxin injections or surgery (i.e. urinary diversion or augmentation cystoplasty)[1]. It should be kept in mind that as the OAB has complex symptoms, the patient's satisfaction should be the main goal in its management[6,7]. By doing this, the clinician can significantly reduce the economic and health care burden by carefully selecting more effective and safe treatment modalities. So, the objective of writing this review is to comprehensively summarize the etiology of OAB, possible risk factors, assessment of symptoms, diagnosis, critical review of different management options, available resources for patient and clinicians and when to seek specialist opinion in management of OAB.

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Risk factors

For OAB, the age is probably the first and best-known risk factor because it's with increasing age its prevalence increases, reaching up to 30% in peoples of 65 years. The urinary infection is another commonest risk factor and nearly 50% of females with OAB symptoms also reported urinary tract infection. The Lower Urinary Tract Symptoms (LUTS) which defines OAB has reported that 12.8% of female has infection as compared to 10.8% in male. The race is another risk factor for OAB that it is more common in Hispanic and African Americans[3]. Other risk factors for OAB are Body Mass Index (BMI) of more than 30 kg/m2, smoking and high caffeine intake (more than 400 mg/d). The post-menopausal females have also been reported with high prevalence of OAB symptoms[3,4]. Although, the female having pelvic organ prolapse reported high prevalence of OAB but no consistent evidence has been demonstrated a correlation among the stage of prolapse or with prolapse compartment[2]. Literature, shows that the surgical or conservative (with Pessary) treatment of prolapse has resulted in marked improvement in symptoms of OAB. Some pelvic surgical procedures are also associated with high prevalence of OAB symptoms. For example, in Colpo-suspension and mid-urethral sling surgery the prevalence of de novo OAB symptoms are reported by 15% and 29% of patients respectively within 1-3 months of surgery[4,5,7]. Finally, the neurologic diseases which affect the lower urinary tract has also reported to be associated with OAB symptoms. The identification of modifiable risk factors is very helpful in management of OAB[4].

Evaluation of OAB

The diagnosis is mainly clinical and based on exclusion and identification of other pathologies. Therefore, a meticulous and detailed evaluation of the symptoms of OAB is an integral step in clinical evaluation[4]. During information gathering, a thorough assessment of duration of symptoms and baseline urinary function is the key component in determining whether the OAB symptoms are bothering the patient and if yes than up to what extent. A validated questionnaire is an appropriate tool in quantifying the patients' symptoms and level of concern to the patient from symptoms. Commonly, the ICIQ OAB or ICIQ-UI SF, are used and reported very helpful. These questionnaires are also helpful in follow up of these patients to assess the improvement in the symptom and to objectively evaluate the efficacy of the different available treatment modalities. During evaluation, all medicines which are used by the patient for other medical conditions, should also be reviewed. Other than that, the co-morbidities like diabetes, hypertension, asthma, cardiac illnesses, sleep apnea etc should also be evaluated meticulously, because these can be a potential contributor in the symptoms of OAB. Similarly, in the presence of other red flag symptoms, like dysuria, haematuria, pelvic pain, dyspareunia, prolapse of pelvic organ and other neurological disorders, alternate diagnosis should be considered or excluded[4,8,9]. A three-day bladder diary is a very good tool in assessing an objective measure of patient's daily fluid intake, types of fluids used and patients voiding habits[9]. A post-void residual urine assessment should also be done to assess the emptying of the bladder especially in patients having neurological disease, obstructive urinary symptoms or done before surgery for the prolapse, urinary incontinence or prostatic pathologies[10].

A detailed and focused physical examination of the patient with special emphasis to the abdomen, genito-urinary and lower extremity edema assessment should be performed. The neurological examination of genital area should also be considered in patients with stroke, diabetes, multiple sclerosis and spinal injury[6,11].

Laboratory investigations should comprise of urine routine analysis to rule out haematuria and infection. In refractory or more complicated patients, like who had pelvic reconstructive surgery or those patients whose symptom has not improved by 1st line and 2nd line therapy, additional assessment like cystoscopy, urodynamic evaluation, imaging of genito-urinary tract to be conducted to differentiate the OAB from other causes[4,11].

Management:

Treatment guidelines for the treatment of OAB are given by different international and national associations (Table-i). To meet this criterion, the first-line therapy and second-line therapy for OAB must be failed on the patient[2,7,12].

Table-I: The recommendations of different associations for overactive bladder therapy.

Level of therapy	Type of therapy	Examples of therapy
First-line therapy:	Behavioral therapy	Bladder diet, bladder training, pelvic floor physical therapy, and biofeedback
Second-line therapy	Medical therapy	Anticholinergic medication and β3 agonist medication
Third-line therapy	Botulinum toxin A/ Neuromodulation	Botox, SNS, and PTNS
Surgery	Augmentation	Cystoplasty

Conservative Options[2,13-19]

Generally, the conservative management options are broadly categorized in two types:

a. Lifestyle modifications.
Control techniques.

Lifestyle modifications comprises of a different of behavior changes which can either minimize, or reduce and even abolish the OAB symptoms. Majority of the life style adjustments are personal experience or opinion based or with a very limited literature or scientific evidence due to the scarcity of clinical trials. These modifications comprise of

- Low fluid intake to (up to 6 to 8 daily glasses of water) and to avoid intake of liquids two to three hours before sleep in order to decrease urine production overnight.
- Decrease bladder irritants intake as a routine like artificial sweeteners, carbonated beverages, caffeine, fizzy drinks, spicy food and alcohol.

- Smoking cessation
- Managing constipation
- Optimization of overall health by weight reduction, better and improved control of modifiable risk factors like diabetes, hypertension, sleep apnea.
- Better control of chronic diseases, reduction in urine production and improving the neurological functions of the bladder with medications.

Control techniques comprises of bladder retraining/Pelvic Floor Muscle Training (PFMT). The recommendation of NICE 2019 are to offer bladder training for at least weeks to the patient with OAB as a first-line treatment. If the women fail to achieve satisfactory improvement from these bladder training sessions, then a combination bladder training sessions and medicine for OAB must considered especially if increase frequency of urine is a bothersome symptom. The Bladder re-training exercises comprises of urges control techniques and scheduled toileting training. The literature has reported that the supervised PFMT of three months duration has been effective in improving the symptoms of urinary incontinence. PFMT sessions should comprise of at least eight contractions, three times each day. Bio-feedback or electrical stimulation should also be considered among those females who are unable to contract their pelvic floor muscles actively as an aid to motivation and adherence to the therapy[20,21].

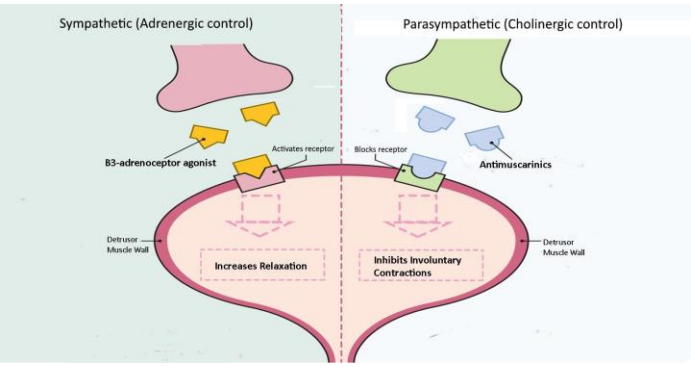

Figure-1: Diagram shows the mechanism of action of anticholinergic and mirabegron. (adopted from Wein et al)[5]

Pharmacological treatment:

For non-invasive conservative management of OAB, the pharmacological treatment options are considered as a second-line treatments and recommended in the NICE/AUA guidelines on OAB. Traditionally, the anti- muscarinic drugs are prescribed, but recently the β3 agonists drugs has been used and also approved in the treatment of OAB. The anti-muscarinic agents have been reported to be safe for long term use and more effective option for the treatment of OAB without or with urine infection[22,23]. The anti–muscarinic drugs decrease the contractility of the bladder by competitively inhibiting the post ganglionic acetylcholine receptors (M2, M3) (5)(Figure-1).

Meta-analysis by Drake et al[23] and a randomized controlled trial by Masaki and colleagues[12] in which they used fixed-effects regression models over more than 27,000 females has concluded that the OAB symptoms improvement with anticholinergic drugs only is modest and rarely successful in resolving the symptoms fully. These drugs provide incomplete symptom relief in majority of patients. Whereas, the patients with OAB symptoms value more to their symptom relief. Therefore, the clinician treating the OAB and their patients' needs to fully understand the limitations of drug treatment and set their expectations accordingly while determining this treatment modality. The main issue among different pharmacological agents is their side effects and merely any difference among their efficacy because these agents effectively reduce the symptoms in approximately 50% of patients[1,22]. The commonly reported side effects of these drugs are blurred vision, dry mouth, urinary retention, constipation, blurred vision, cognitive changes and dyspepsia. The long- term effects of anticholinergic drugs on patients' cognitive function are uncertain[2]. Due to these bothersome side effects, the compliance of these anti-muscarinic is usually low among the patients[14].

The commonly available or in use antimuscarinic agents for OAB management all over the world are Oxybutynin, Tolterodine, Fesoterodine, Trospium, Darifenacin, and Solifenacin. The American Urological association (AUA) and European Association of Urology (EAU) has conducted an extensive review of the randomized controlled trials in which these drugs are evaluated for management of OAB and has not found any statistically significant convincing evidence about differential efficacy among all these drugs[6,7]. Therefore, drug selection for OAB is mainly depends on various factors that like age of patient, side effect profile, and drug cost. The NICE 2019 guidelines had recommended that at least four-week drug treatment trial with a lowest acquisition cost should be offered to the patient[2].

In past, only oral medications for bothersome OAB available to patients are antimuscarinic agents. In 2012 the FDA (Food and Drug Administration Authority) has approved the Mirabegron in the treatment of OAB which is a β3 adreno-receptor agonist, and effective in promoting the detrusor muscle relaxation (Figure-1)[12]. Mirabegron is recommended by the NICE Technology Appraisal Guidance [TA290] 2013 as a second line medical therapy among those in which the anticholinergic drugs are clinically ineffective or contraindicated or these patients having unacceptable side effects. In recommendations, it can be considered as a therapy among more than 65-year-old patients with cognitive deficit[2,23]. The increased risk of hypertension has been reported the major adverse effect or concern with the use of this drug. Other side effects reported with this are uncommon for example less than 2% of patients reported constipation or dry mouth. This has made Mirabegron a more desirable option as compared to anti-muscarinic drugs for most of the patients. Vibegron (Urovant) potential new drug under trial for the management of OAB which will avoid risk of hypertension[17,23].

The Intravaginal estrogen's is recommended in the treatment of OAB symptoms among post-menopausal females with evidence of vaginal atrophy[2,6].

A combination therapy with Solifenacine and Mirabegron has been approved and recommended in 2018 by the Food and Drug Administration (FDA)[22,24]. In a randomized, double-blind phase

II study by Masaki et al[12], the combination therapy with Solifenacine and Mirabegron has demonstrated statistically significant improvement of symptoms over mono-therapy with Solifenacine 5 mg. The side effects have not reported to be more compared with Mirabegron or Solifenacine monotherapy, except a slightly higher frequency of constipation.

It is recommended that the patients who remains on long term medical treatment for the management of OAB, should be followed and reviewed regularly at the primary health care facility after every twelve months, and after six months if they are above 75 years of age for the development of side effects, efficacy of drugs and improvement in symptoms[2].

Treatment of refractory OAB

The failure to managing the OAB with conservative treatment, with conventional means and by pharmaco-therapeutic modalities usually leads to the refractory state of OAB. Literature shows many discrepancies in "refractory OAB" definition. It could be defined as "the loss of efficacy or absence of any effect or inability to continue with treatment due to contraindication or side effects of the treatment[25]. Given its radical and drastic, the surgery is usually the last resort. The debate is between the intra-vesical botulinum toxin inj treatments or neuro-modulation is ongoing that which one is the best intermediate option. The patients which met the criteria of refractory OAB, are suitable for the 3rd line management[22,25,26].

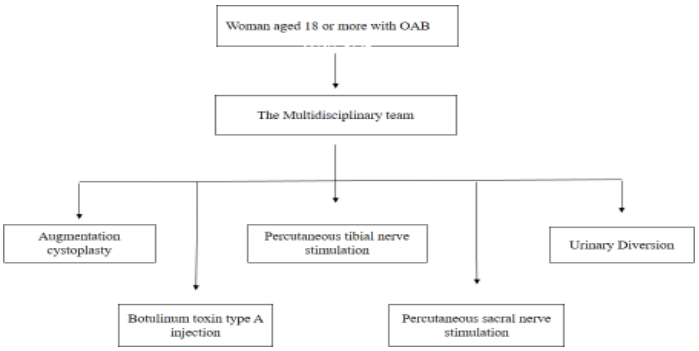

Figure-2A: NICE pathway for refractory OAB.2

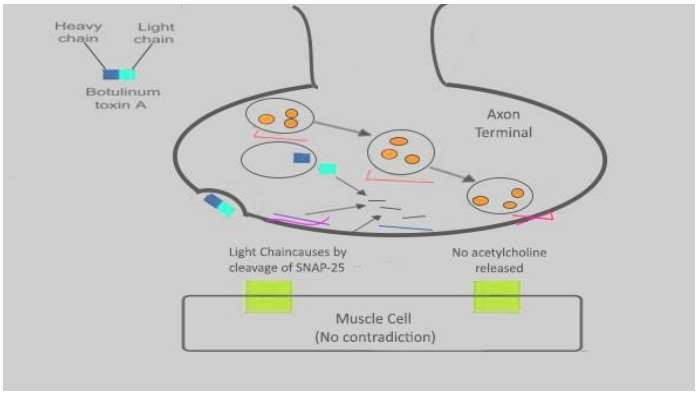

Figure-2B: Diagram showing mechanism of action of Botulinum toxin type A. (adopted from Tremaine et al)[27]

The FDA in 2013 has approved the Botox® (Onabotulinum toxin A) (Allergan, Inc., Irvine, CA, USA), as a treatment option for idiopathic OAB. More recently the Medicines and Health Products Regulatory Agency (MHRA) has also approved the use of Onabotulinum toxin A (Botox®) in the management of neurogenic and idiopathic detrusor overactivity. Surgically, the Botulinum toxin is directly injected in the detrusor muscle located in the postro-inferior urinary bladder wall[1,22]. (Figures-2A and 2B)

In systematic review and network meta-analysis by Kelleher and colleagues, they analyzed 56 RCTs in which botulinum toxin A injection therapy were compared with other pharmaco-therapies, and observed that therapy with botulinum toxin A injection is more effective in relieving symptoms of OAB. The efficacy of Botox injection ranges from 36% to 89% with a mean of 70% and its effect last from four months to ten months with a mean of 6 months effectiveness. They concluded that in neurogenic detrusor overactivity, the Botulinum toxin A therapy is more effective[28].

The 3rd line treatment modality also comprises of neuro-modulation of the nerves which control the functions of the bladder function. The two discrete modalities of neuro-modulation treatment comprise of Peripheral Tibial Nerve Stimulation (PTNS) and Sacral Neuro Modulation (SNM). The FDA has approved the Sacral Neuro Modulation in 1997 (InterStim®). The NICE guidelines in 2019 recommended that the SNM should be offered to the patients after discussion in local MDT, if the patient is unwilling for CISC or in case there is no response to conservative treatment and injection of Botulinum toxin A[25,29]. The SNM comprises of the stimulation of the afferent neural pathways which mainly controls the bladder function via sacral nerve plexus. Through this way (Sacral nerve plexus) the normal voiding and storage function functions of the bladder are restored and not affected. Unlike the PTNS, this modality of sacral neuro-modulation is carried out with a surgical implant placed in body permanently. So, it's very important to test this modality as a first step phase and if patient shows good response than they can have this implant placed permanently [19,25,30]. Literature has reported that almost 50 to 88% of patients respond to the initial test phase. The main issue with this is that once implanted permanently, the generator battery lasts for about five years on average, which than needs to be replaced surgically. The adverse events reported are pain at site of implantation, infection, adverse change in voiding of bowel functions, lead migration, technical or device problems, and undesirable stimulation. Currently, the Axonics is an effective and only rechargeable SNM system available in market which is designed to reduce the battery replacement invasive procedures which is needed after every 3 to 5 years with a non-rechargeable system. The other advantage of this system is that it's also smaller in size than other non-rechargeable SNM devices available in market. It is also claimed to having low risk of implant site pain and also more suitable for the patients with low BMI. Another advantage of this system is that it is not contraindicated in MRI scanning so can be used in whole body MRI whereas the Interstim is only approved for head MRI[25,29,30].

Contraindications to the SNM comprises of inadequate patients' response during test phase, patient needing frequent MRI for other pathologies and use of diathermy. The Sacral Neuro Modulation demonstrate a substantial improvement (61%) in OAB symptoms, urinary frequency (61%), and urge incontinence episodes (71%)[30,31]. However, EAU Guideline 2019 (ROSETTA trial) states that the SNS is not more effective than Botox 200 U at six months followup[10,32].

In 2005, the US Food and Drug Administration (FDA) has approved the PTNS under the commercial name of Urgent PC® (Uroplasty, Minnetonka, MN, USA) for the management of refractory OAB. The treatment is carried out with the stimulation from the posterior tibial nerve to the afferent nerves of the sacral plexus. This treatment is recommended for a period of 12 weekly and each session should be of 30 minutes, followed by gradually tapered treatment over several weeks or months. The ongoing treatment is recommended to be continued as and when needed to maintain the relief of OAB symptom. The treatment response usually can be observed as early as after first session, but the response may take up to the six sessions. Therefore, it is recommended to complete the all 12 sessions before re-evaluating the patient. No serious side effects of PTNS have been reported in literature PTNS[14,33].

NICE 2019 guidelines, do not favour the trans-cutaneous sacral nerve stimulation or trans-cutaneous posterior tibial nerve stimulation in the treatment of OAB in female[2,34]. The NICE 2013 guideline has recommended the augmentation cystoplasty for the management of detrusor overactivity only in case the non-surgical options has failed and patient is willing for and is able to self- catheterize[2,11]. Similarly, the urinary diversion option only given to those patients in which less invasive therapies are failed or ineffective and are consented to accept a stoma. These patients should also be warned regarding the possible minimal risk of malignancy during counselling session [2, 5, 24,35].

When to refer?

By this review, the information's provided, clinicians should now be able to guide their patients more precisely regarding assessment, diagnosis and different treatment options available for OAB. The 1st and 2nd line therapy can be offered to the patients at primary care level. For 3rd line therapy, the referral to the specialist or center is recommended, who or where these procedures are carried out regularly. The suitable candidates for 3rd line therapy are those patients, in which conservative management (1st line therapy), and either two medications (2nd line therapy) have been unsuccessful or those who are unable to tolerate medical treatment due to their adverse effects or having contraindications to drug treatment[32,33].

Take home message:

- Over Active Bladder is not a life-threatening condition.
- The treatment benefits should be considered cautiously against the possible side effects and that in this case not offering any treatment is more suitable and acceptable option for the patient.
- Innumerable factors contribute in selecting anti- muscarinic drugs like the necessity for molecular structure which is pharmacologically favorable, drug's pharmacokinetic profile, a titratable formulation to improve compliance in daily dosing, less adverse effects, cost-effectiveness of treatment which is always considered for insurance coverage and out-of- pocket costs.
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- The Botulinum toxin injection therapy is very effective option both clinically and economically in the management of refractory OAB.
- The Sacral Neuro-modulation (SNS) has been reported having promising results with up to 70% success rate in refractory OAB management.

Surgical option should be considered as a last resort when non-surgical modalities has been proved ineffective.

CONCLUSION

Over Active Bladder is a complex prevalent health problem, affecting millions of adults all over the world. Precise assessment of symptoms, identification of individuals with risk factors and diagnosis of OAB by exclusion is mandatory. Several promising treatment options are available currently to manage this pathology. It is mandatory to empower and counsel your patients to seek medical advice and recognize this diagnosis in order to manage it appropriately.

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