THE PREVALENCE, IMPACT AND MANAGEMENT OF URINARY INCONTINENCE IN THE FEMALE POPULATION OF THE USA

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Urinary incontinence is estimated to affect up to 30% of women in the USA, although differences in the populations studied and the definition of urinary incontinence have contributed to wide variations in estimates of its prevalence. The number of women with overactive bladder (characterised by symptoms of urinary frequency and urgency with or without urge incontinence) is likely to be even higher. Although bladder symptoms are relatively common and have a significant negative impact on their quality of life, many women fail to seek treatment, believing that their symptoms are a consequence of aging or childbirth. Instead, they may adopt complex coping strategies, such as the use of protective pads. Behavioral techniques, such as Kegel exercises and bladder training are useful first-line treatments for stress and urge incontinence, respectively. In addition, women with urge incontinence as well as symptoms of frequency and urgency may also be treated successfully with an antimuscarinic agent, such as tolterodine (Detrol LA®/Detrusitol SR®). Public education programs to raise awareness about urinary incontinence and its treatment aim to improve communication between physician and patient to ensure that bladder symptoms are recognised and treated appropriately. Secondo le ultime stime, l’incontinenza urinaria che colpisce le donne degli Stati Uniti d’America raggiunge il 30%, anche se le differenze rilevate nelle popolazioni studiate e la definizione di incontinenza urinaria hanno contribuito ad espandere le variazioni nelle stime di tale diffusione. È molto probabile, però, che il numero di donne che possiede un’iperattività vescicale (caratterizzata dai sintomi di urgenza e frequenza urinaria che si associano o meno all’incontinenza da urgenza) diventi sempre maggiore. Sebbene i sintomi che riguardano la vescica siano relativamente comuni e abbiano un significativo impatto negativo sulla qualità della vita, numerose donne non richiedono alcun trattamento, nella convinzione che i loro sintomi siano conseguenza dell’invecchiamento o del parto. Molte donne, invece, adottano complessi metodi di contenimento personali, come l’utilizzo di tamponi protettivi. Le tecniche comportamentali, come gli esercizi di Kegel e il Training della vescica risultano trattamenti utili e fondamentali rispettivamente per l’incontinenza da urgenza o da stress. In aggiunta, le donne che presentano un’incontinenza da urgenza o sintomi di urgenza e frequenza possono ricevere un trattamento dagli esiti positivi utilizzando un agente antimuscarinico, come ad esempio la tolterodina (Detrol LA®/Detrusitol SR®). I programmi pubblici di istruzione nei riguardi dell’IU e del relativo trattamento hanno come obiettivo il miglioramento della comunicazione tra medico e paziente per un trattamento appropriato dei sintomi vescicali.
INTRODUCTION

Bladder symptoms and urinary incontinence may affect up to one-third of women in the USA. Although most epidemiological studies have focused on women who experience involuntary loss of urine, there is increasing recognition that overactive bladder (OAB), which is characterized by symptoms of urinary frequency and urgency, with or without urge incontinence, is also widespread among women. Regardless of the nature and cause of their symptoms, many women do not seek treatment for their bladder symptoms, either due to embarrassment or because they believe that urinary incontinence is an inevitable consequence of childbirth or aging. In addition, many patients and their families are not aware that effective treatments are available. This article reviews the prevalence and treatment of urinary incontinence and OAB in women in the USA, and considers the importance of public education programs in ensuring that patients receive the most appropriate treatments for these distressing symptoms.

DEFINING URINARY INCONTINENCE

Before considering the prevalence of urinary incontinence among women in the USA, it is necessary to define exactly what is meant by urinary incontinence. The International Continence Society (ICS) defines it as “a condition where involuntary loss of urine is a social or hygienic problem...
and is objectively demonstrable’ [1]. This broad definition encompasses several different manifestations, including the two most common forms of urinary incontinence: stress incontinence and urge incontinence. In stress incontinence, there is involuntary loss of urine associated with increased intra-abdominal pressure (e.g. when coughing, sneezing, laughing or lifting heavy objects), which is due to failure of the urethral sphincter. Urge incontinence is the involuntary loss of urine associated with a strong desire to void (urgency). Many patients have mixed incontinence (i.e. symptoms of both stress and urge incontinence) [1]. However, there is increasing recognition that many women suffer from the condition of OAB, in which there are involuntary contractions of the detrusor muscle during the storage phase of the micturition cycle. These contractions give rise to symptoms of urinary frequency (≥ 8/24 hours), urgency (a strong desire to void), with or without urge incontinence (urine loss if the desire to void cannot be suppressed) [1], and may also cause nocturia (waking more than once at night to urinate). The natural history of OAB is not fully understood, but it has been suggested that symptoms of frequency and urgency may progress to symptoms of urge incontinence.
The prevalence of bladder symptoms in the population is hard to define and reported estimates vary greatly. The reasons for the disparity are numerous: there is no unifying definition for urinary incontinence or for OAB and the ICS definitions of incontinence or OAB are not specific enough for prevalence investigations. Therefore, the outcomes of existing prevalence studies are affected by the definition of severity or type of incontinence [2]. For example, a study that measures the prevalence of incontinence based on only one symptom (e.g. level of urine leakage) is likely to report a different prevalence rate than a study that distinguishes between the various types of incontinence. In addition, many prevalence studies have been based upon questionnaire surveys that have not been validated using objective clinical assessments [1, 2]. This is particularly important as the questionnaires should have low sensitivity (to identify all potential patients) and high specificity (in terms of definitions of bladder symptoms). For example, in a meta-analysis of epidemiological studies of urinary incontinence, Hampel and colleagues [1] found that, although almost all surveys asked specific questions to identify stress incontinence, only about half of the studies included questions specifically designed to identify urge incontinence.

The issues surrounding prevalence estimates extend to the measurement of OAB also. The majority of studies carried out have investigated only in-
continence, and have not taken into account the symptoms of frequency and urgency, even though about half of those with OAB do not present with urge incontinence [3]. No validated OAB-specific questionnaires have been developed with which to investigate the prevalence of OAB.

For these reasons, it has been recommended by specialists at the first International Consultation on Incontinence that the measurement instruments for bladder symptoms in community surveys should be standardized for worldwide use [2].

Overall, approximately 13 million people in the USA are thought to suffer from urinary incontinence, with prevalence being greater in women than in men [2]. Estimates suggest that the prevalence of urinary incontinence in women may be as high as 30%. For example, one survey of 541 healthy women aged between 42 and 50 years in Pittsburgh found that 58% had experienced involuntary loss of urine at some time, while 31% had regular episodes of incontinence, with at least one episode per month [4]. In general, the prevalence of incontinence increases with age (Table 1) and with childbirth [5].

A review of 21 studies found that in women with urinary incontinence, an estimated 49% had stress incontinence, 29% mixed incontinence and 22% urge incontinence [1].

Prevalence estimates for OAB range from 17 million to 71 million in the USA [9]. This means that, even at the lower end of the range, OAB is more prevalent than diabetes or gastrointestinal ulcer and as prevalent as asthma and chronic bronchitis [10].

I problems that the stime sulla diffusione si estendono anche alla misurazione del fenomeno OAB. La maggior parte degli studi eseguiti hanno analizzato solo l’incontinenza, non tenendo in alcuna considerazione i sintomi di frequenza e di urgenza, anche se circa la metà di coloro i quali soffrono di OAB non presentano incontinenza da urgenza [3]. Non sono stati sviluppati questionari convalidati specifici sull’OAB con i quali analizzare la diffusione di OAB.

Per tali ragioni gli specialisti hanno raccomandato, in occasione della prima Consultazione Internazionale sulla Incontinenza, che gli strumenti di misurazione relativi ai sintomi relativi alla vescica nelle indagini a livello collettivo debbano essere standardizzati per un utilizzo su scala mondiale [2].

Nel complesso, approssimativamente 13 milioni di persone negli Stati Uniti d’America soffrono di incontinenza urinaria, con una diffusione maggiore tra le donne rispetto agli uomini [2]. Le stime suggeriscono che tale diffusione di incontinenza urinaria nelle donne possa raggiungere il 30%. Un’indagine su 541 donne sane di età compresa tra i 42 e i 50 anni, condotta a Pittsburgh, ha evidenziato, ad esempio, che il 58% delle intervistate ha subito alcune volte una perdita involontaria di urina, mentre il 31% sperimenta episodi periodici di incontinenza, che registrano almeno un episodio al mese [4]. In generale, la diffusione dell’incontinenza aumenta con l’età (Tabella 1) e con il parto [5].

Un esame condotto su 21 studi ha rilevato che nelle donne che presentano incontinenza urinaria, il 49% soffre di incontinenza da stress,
An ongoing study of the prevalence of OAB in the US population, known as the National Overactive Bladder Evaluation (NOBLE) Program, will be the first to use a validated, OAB-specific questionnaire. The NOBLE Program will be the largest US study of bladder symptoms to date, with a planned recruitment of over 7000 individuals. It is anticipated that the data from this study will define the prevalence, impact and burden of OAB in the USA [11, 12].

**INCIDENCE OF BLADDER SYMPTOMS**

Few studies have sought to investigate the incidence of bladder symptoms. In one study, the cumulative incidence of chronic incontinence in previously continent women aged between 42 and 50 years was 8.0% over 3 years [4]. However, a study per-29% di incontinenza mista e il 22% di incontinenza da urgenza [1].

Le stime sulla diffusione di OAB sono comprese tra i 17 milioni e i 71 milioni negli Stati Uniti d’America [9]. Ciò significa che, persino se si considera il valore più basso dell’intervallo, il fenomeno di OAB è più diffuso rispetto al diabete o all’ulcera gastrointestinale ed è diffuso al pari di asma e bronchite cronica [10].

Uno studio in corso relativo alla diffusione di OAB nella popolazione degli Stati Uniti, conosciuto come Programma NOBLE (National Overactive Bladder Evaluation), sarà il primo a utilizzare un questionario convalidato specifico sull’OAB. Il Programma NOBLE sarà il più vasto studio statunitense sui sintomi relativi alla vescica mai eseguito, con un reclutamento pianificato di oltre 7000 individui. E’ stato anticipato che i dati derivati da questo studio definiranno la diffusione, l’impatto e la portata di OAB negli Stati Uniti d’America [11,12].

**Table 1 - Prevalence of urinary incontinence in US women according to age.**

<table>
<thead>
<tr>
<th>Population</th>
<th>Prevalence</th>
<th>Reference</th>
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<tr>
<td>Women aged &gt;60 years</td>
<td>38%</td>
<td>[6]</td>
</tr>
<tr>
<td>Institutionalized elderly</td>
<td>≥50%</td>
<td>[7, 8]</td>
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INCIDENZA DEI SINTOMI RELATIVI ALLA VESCICA

Pochi studi hanno tentato di analizzare l’incidenza dei sintomi relativi alla vescica. In uno studio, l’incidenza cumulativa dell’incontinenza cronica in donne precedentemente continenti di età compresa tra i 42 e i 50 anni era l’8.0% in un periodo di 3 anni [4]. Uno
formed in women aged between 65 and 104 years found that the incidences of stress and urge incontinence over a 3-year period were 28.6% and 28.5%, respectively [13]. In a study in a managed-care setting in the USA, the incidence of incontinence and OAB was determined to be 1.4% and 1.0%, respectively. The researchers noted the low incidence was probably due more to underreporting than to the lower age of the patients studied [14].

**IMPACT OF BLADDER SYMPTOMS ON QUALITY OF LIFE**

The impact of bladder symptoms on health-related quality of life (HRQoL) can be dramatic, as the symptoms influence many aspects of daily living, including psychological well-being, social and physical functioning, relationships and activities *(see Figure 1).* Urinary incontinence has a significant impact on social and psychological function, compared with age-matched controls [15], and also affects the lives of carers of the elderly or disabled [10].

It has been reported that urge incontinence has a greater impact on HRQoL than stress incontinence. This may be due to the unpredictability of the condition as well as the greater volume of fluid that is lost in urge incontinence, as well as lack of sleep due to nocturnal enuresis and nocturia. A study of employed women with urge incontinence recorded their concerns about job seeking and performance at work as a result of their

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*L’apparato genitale femminile (uroginecologia)*

Studio eseguito tra donne di età compresa tra 65 e 104 anni ha tuttavia rilevato che le incidenze di incontinenza da stress e da urgenza in un periodo di 3 anni erano del 28.6% e del 28.5% rispettivamente [13]. In uno studio condotto in ambito ospedaliero negli Stati Uniti d’America, l’incidenza dell’incontinentenza e di OAB è stata attestata a 1.4% e 1.0% rispettivamente. I ricercatori hanno individuato come causa della bassa incidenza non tanto la più giovane età dei pazienti studiati quanto una sottostima nelle segnalazioni [14].

**IMPATTO DEI SINTOMI RELATIVI ALLA VESCICA SULLA QUALITÀ DELLA VITA**

L’impatto dei sintomi relativi alla vescica sulla qualità della vita in relazione alla salute (HRQoL) può essere drammatico, poiché i sintomi influiscono su molti aspetti della vita quotidiana, inclusi il benessere psicologico, il funzionamento fisico e sociale, le relazioni e le attività *(vedi Figura 1).* L’incontinentenza urinaria ha un impatto significativo sulla funzione psicologica e sociale, messa in relazione ai controlli corrispondenti all’età [15] e influenza inoltre sulle vite di coloro che si prendono cura degli anziani o dei disabili [10].

E’ stato indicato che l’incontinentenza da urgenza possiede un impatto maggiore sulla HRQoL rispetto all’incontinentenza da stress. Ciò può essere determinato sia dalla imprevedibilità della condizione sia dal maggiore volume di fluido perso nel caso dell’incontinentenza da urgenza, sia infine dalla mancanza di sonno dovuta alla enuresi notturna e alla nicturia. Uno studio su donne
These women also reported that they felt unattractive, had low self-esteem and that urinary incontinence had an adverse effect on dating and sexual activities. Lenderking and colleagues [18] also found that fear of incontinence impaired sexual activity, as some women experience leakage during intercourse. Furthermore, it has been documented that the impact of OAB on HRQoL is greater than that seen with diabetes or hypertension [10, 19] (Figure 2).

There are few data on the impact of OAB without incontinence; although it has been suggested that patients with symptoms of frequency and urgency experience a decrease in HRQoL similar to patients with urge incontinence [20] [16]. The NOBLE Program has found that the symptoms of frequency and urgency impart a
clinically significant reduction in quality of life, compared with the normal population [21]. As the prevalence of continent OAB patients is estimated to be very high, the economic impact is likely to be greater than that attributed to urge incontinence [10].

**HELP FOR THE WOMAN WITH URINARY INCONTINENCE**

Healthcare-seeking in those with bladder symptoms

Despite the high prevalence and significant impact on HRQoL of OAB non associato all’incontinenza; sebbene è stato suggerito che i pazienti con sintomi di frequenza e urgenza subiscano una diminuzione della HRQoL simile a quella dei pazienti con incontinenza da urgenza [20] [16]. Il Programma NOBLE ha rilevato che i sintomi di frequenza e di urgenza determinano una riduzione clinicamente significativa nella qualità della vita, a paragone con la popolazione normale [21]. Poiché la stima della diffusione dei pazienti di OAB continenti è molto alta, è probabilmente che l’impatto economico sia maggiore rispetto a quello attribuito all’incontinenza da urgenza [10].

**SUPPORTO PER LE DONNE CON INCONTINENZA URINARIA**

Ricerca sanitaria fra coloro che soffrono di sintomi relativi alla vescica

Nonostante la grande diffusione e l’impatto significativo sulla HRQoL dei

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**Figure 2 - OAB has a greater impact on HRQoL than diabetes or hypertension [19].**

![Impact of Overactive Bladder on Quality of Life Compared to Other Conditions](image)

*Kohiti-Phuay et al. 27th annual meeting of ICS, 1997.
BP = bodily pain; GH = general health perceptions; MH = mental health; PF = physical functioning; RE = role of limitations (emotional); RF = role of limitations (physical); SF = social functioning; V = vitality.*
der symptoms, only a small proportion of women with urinary incontinence or OAB seek treatment for their condition, and they tend to seek help only when symptoms are severe (see Figure 3) [Burgio, 1991 #25; [20].

Furthermore, women are less likely than men to have consulted a physician about their symptoms of urinary incontinence [22]. For example, although the prevalence of urinary incontinence in women over 50 years of age is approximately double that in men (48.7% versus 24.3%), only 13% of the women had consulted a physician about their symptoms in the previous year compared with 29% of the men.

Patients with bladder symptoms are often embarrassed about discussing their symptoms and believe that the symptoms are a natural consequence of childbirth or aging. They
are not aware that effective treatment is available. This is compounded by the fact that bladder function is not included in routine consultations with family practitioners, even for high-risk patients. [23]

Coping strategies

Rather than seeking help for their bladder symptoms, most sufferers develop coping strategies.

The MESA survey found that just over half of women with urinary incontinence used absorbent materials to manage their urine leakage [24]. Incontinence pads are available at pharmacies, but the costs are generally not reimbursed by the medical insurance companies. Consequently, the full cost of these items is borne by the patient. As much as US$4.5 billion is spent each year on incontinence pads. Although the use of absorbent materials enables the patient to deal with the immediate problem of leakage, it does not address the cause of urinary incontinence. Furthermore, pad use also leads to skin irritation and infection [25, 26].

More complex coping strategies may be implemented to cope with the symptoms of frequency and urgency, including dietary changes and fluid restriction at night, bathroom-seeking immediately upon arrival at an unfamiliar place and planning restroom visits [24]. Wyman and colleagues [27] found that activities involving unfamiliar places where the availability of toilets was not known, such as shopping, entertainment, guenza naturale del parto o dell’invecchiamento. Esse non sono consapevoli del fatto che è disponibile un trattamento efficace. Tale problema è accentuato dal fatto che la funzionalità della vescica non è considerata nei consulti di routine che si hanno con il medico di famiglia, persino per i pazienti ad alto rischio. [23]

Metodi di contenimento personali

Piuttosto che chiedere supporto per i sintomi relativi alla vescica, la maggior parte di coloro che ne soffrono sviluppano dei metodi di contenimento personali.

L’indagine MESA ha rivelato che più della metà delle donne che soffrivano di incontinenza urinaria utilizzavano materiali assorbenti per gestire le loro perdite di urina [24]. I tamponi per l’incontinenza sono disponibili nelle farmacie, ma il loro costo non è, in generale, rimborsato dalle compagnie assicuratrici mediche. Di conseguenza, l’intero costo di questi articoli grava sul paziente. Negli Stati Uniti ogni anno si spendono $4,5 miliardi in tamponi per l’incontinenza. Anche se l’utilizzo di materiali assorbenti consente al paziente di gestire nell’immediatezza il problema della perdita, esso non risolve la causa dell’incontinenza urinaria. L’utilizzo del tampone, inoltre, determina anche infezioni e irritazioni della pelle [25, 26].

E’ possibile attuare metodi di contenimento personali più complessi per far fronte ai sintomi di frequenza e urgenza, incluse modifiche alla dieta e limitazioni di fluidi durante la notte, la ricerca immediata del bagno all’arrivo in luoghi sconosciuti e la pianificazione della frequenza con cui si va al ba-
long-distance travel and vacations, were seriously affected by urinary incontinence and OAB. While the adoption of coping strategies may lessen the incidence of ‘accidents’, they add to the burden of the disease [10]. Furthermore, although the coping strategies may begin as minor changes to daily activities, they may progress to such a level that sufferers are prevented from carrying out their usual activities, for example avoiding travelling or visiting relatives.

Role of primary care

The family practitioner is often the first person who women with urinary incontinence consult, but individual healthcare plans may permit them to consult directly with a urologist or a gynecologist without referral from a primary care physician. For elderly patients, a geriatrician is often the first person to diagnose and treat their condition.

However, before any consultation takes place, both patient and physician need to be aware of the need to evaluate and treat symptoms. At present, there are no formal tools available to assist and encourage communication between doctors and patients about bladder symptoms. Furthermore, OAB was not classified as a disease under the International Classification of Diseases (ICD version 9),

gno [24]. Wyman e collaboratori [27] hanno evidenziato che le attività che coinvolgevano luoghi sconosciuti nei quali la disponibilità delle toilette non era nota, come ad esempio negozi e luoghi di divertimento, vacanze e viaggi a lunga distanza, erano seriamente pregiudicate dall’incontinenza urinaria e dal fenomeno di OAB. Anche se l’adozione di metodi di contenimento personali può ridurre l’incidenza di “infortuni”, tutte queste accortezze si aggiungono al pesante carico della malattia [10]. In aggiunta, sebbene i metodi di contenimento personali possono incidere inizialmente come modifiche minori alle attività giornaliere, queste possono progredire a un livello tale da impedire ai malati di portare avanti le loro usuali attività, ad esempio evitando viaggi e visite ai parenti.

Ruolo delle cure di base

Il medico di famiglia è spesso la prima persona che le donne con incontinenza urinaria consultano, ma i piani sanitari individuali possono consentire alle pazienti di consultare direttamente un urologo o un ginecologo senza alcuna prescrizione da parte di un medico di base. Per i pazienti anziani, un geriatra è spesso la prima persona a diagnosticare e curare la loro condizione.

Prima che avvenga una consultazione di qualche tipo, comunque, sia il paziente che il dottore devono essere consapevoli della necessità di valutare e curare in modo appropriato i sintomi. Al presente, non esistono strumenti convenzionali disponibili per assistere e incoraggiare la comunicazione tra dottori e pazienti sui sintomi relativi alla vescica. In aggiunta, il fenomeno di
which has inhibited reimbursement for treatment. In addition, although guidelines for the diagnosis and treatment of urinary incontinence have been developed and recently revised by the Agency for Health Care Policy and Research (AHCPR) [28], they are not widely used by primary care physicians in the USA, and do not address the OAB symptoms of frequency and urgency.

**PREVENTION PROGRAMS**

**Initiatives to improve patient–physician communication**

It is generally accepted that the bladder symptoms associated with OAB should be diagnosed and managed in primary care. However, this is dependent upon the development of a clinically validated screening tool.

Communication about bladder symptoms between patient and physician is an important prerequisite for the recognition of those requiring intervention and the allocation of treatment, many of which are effective at lessening the burden of symptoms and increasing HRQoL. In fact, the AHCPR guidelines recommend that patients and their families should be taught that incontinence is not inevitable or shameful, but is a condition that is treatable or, at least, manageable [28].

A number of recent initiatives by the American Urological Association (AUA), the American Foundation for Urologic Disease (AFUD) and the American Medical Women’s Association-
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Table 2 - Website details of key associations and organizations.

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<thead>
<tr>
<th>Organization</th>
<th>Website address</th>
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<tbody>
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<td>AUA</td>
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...for Urological Disease (AFUD) e dall’American Medical Women’s Association (AMWA) hanno cercato di accrescere la consapevolezza verso i problemi legati all’incontinenza urinaria e al fenomeno OAB e di incoraggiare le donne a discutere dei loro sintomi con il loro medico. Iniziative come la National Bladder Health Week (Settimana per la Salute della Vescica a livello Nazionale), organizzata in novembre ogni anno dal Bladder Health Council dell’AFUD, aumentano la consapevolezza del pubblico verso l’incontinenza urinaria e l’OAB. L’AFUD ha inoltre stabilito delle linee telefoniche di soccorso gratuite rivolte ai pazienti e ai loro familiari affinché ottengano informazioni che toccano il campo che riguardano la vescica, il suo stato, le condizioni, ecc. Una vasta gamma di gruppi di supporto a livello pubblico è disponibile per le donne che soffrono di incontinenza urinaria. In aggiunta alle associazioni menzionate in precedenza, tali gruppi contano anche la presenza di organizzazioni internazionali come, ad esempio, Continence Worldwide e ICS, e di organizzazioni...
whole, play an important role in eliminating the taboo associated with bladder symptoms.

The NOBLE Program will also serve to increase awareness of bladder symptoms and will provide a validated questionnaire that can be used in primary care to identify bladder symptoms requiring intervention. The questionnaire will guide diagnosis and management and, importantly, it will prompt discussion between patient and physician. During the Program, patients with OAB will be followed to assess the impact of treatment on their symptoms and lifestyle, and to study the natural history of the condition. It is also hoped that the NOBLE Program may determine whether early treatment of bladder symptoms such as frequency and urgency will help prevent potential progression to urge incontinence.

The AHCPR guidelines also recommend that professional education about the evaluation and treatment of urinary incontinence should be included in both undergraduate and graduate training programs for all healthcare professionals, as well as in continuing education programs. To support this need, the World Health Organization (WHO) has included OAB as a ‘disease’ in the latest revision of the ICD – ICDCM-9.

nazionali come, ad esempio, American Urogynecological Society (AUGS), National Association for Continence, Simon Foundation for Continence e Alliance for Aging Research.

I programmi di istruzione e i gruppi di supporto, diretti a pazienti singoli e al pubblico, giocano un ruolo importante nel tentativo di eliminare ogni taboo associato ai sintomi relativi alla vescica. Il Programma NOBLE sarà utile inoltre per accrescere la consapevolezza verso i sintomi relativi alla vescica e fornirà un questionario convalidato che potrà essere utile nelle cure primarie per identificare i sintomi relativi alla vescica che richiedono un intervento. Il questionario guiderà la diagnosi e la gestione e, cosa più importante, solleciterà una discussione tra paziente e medico. Durante il Programma, i pazienti affetti da OAB verranno seguiti per accertare quale sia l'impatto del trattamento sui sintomi e lo stile di vita, e per studiare l'evolversi naturale della condizione. Si spera che il Programma NOBLE consenta di determinare se il trattamento precoce dei sintomi vescicali, come ad esempio la frequenza e l'urgenza, possa aiutare a evitare la potenziale progressione verso l'incontinenza da urgenza. Gli orientamenti dell'AHCPR raccomandano che venga inclusa l'istruzione professionale relativa alla valutazione e al trattamento dell'incontinenza urinaria sia nei programmi di addestramento universitari e post-universitari per tutti i professionisti della salute che nella continuazione dei programmi d' insegnamento. La World Health Organization (WHO) ha incluso l'OAB come “malattia” nell’ultima revisione dell’ICD – ICDCM-9.
MANAGEMENT OF URINARY INCONTINENCE

A number of different approaches may be employed to manage urinary incontinence, including behavioral therapies, pharmacotherapy and surgery. The choice of treatment for an individual patient is determined by the nature and severity of the symptoms.

Behavioral therapies

Regular daily exercises that strengthen the muscles of the pelvic floor (Kegel exercises) and help to reduce leakage are the first-line therapy for women with mild to moderate stress incontinence [29]. Kegel exercises have been reported to improve mild to moderate stress incontinence in 54% of cases, with remission in 16% of cases [30, 31]. They have also been reported to improve the symptoms of OAB [30, 31]. Biofeedback, which helps women to gain awareness and control of the pelvic muscles, and electrical stimulation of the pelvic floor musculature can be employed to increase the effectiveness of Kegel exercises. Vaginal cone exercises are another method of strengthening the pelvic floor muscles [29], and may be useful in the treatment of women with stress incontinence. Bladder training techniques, in which the patient is taught to resist the urge to pass urine and gradually increase the intervals between voiding, may be used successfully in the treatment of women with urge incontinence and OAB [29] [32]. The aim of bladder training is to increase the capacity of the bladder and so reduce the number of episodes of incontinence [32].

GESTIONE DELL’INCONTINENZA URINARIA

E’ possibile impiegare un numero di approcci differenti nella gestione dell’incontinenza urinaria, incluse le terapie comportamentali, la terapia farmacologica e la chirurgia. La scelta del trattamento per un singolo paziente viene determinata dalla natura e dalla gravità dei sintomi.

Terapie comportamentali

I regolari esercizi giornalieri che rafforzano i muscoli del pavimento pelvico (esercizi di Kegel) e aiutano a ridurre la perdita rappresentano la principale terapia per le donne che soffrono di una forma di incontinenza da stress che varia da lieve a moderata [29]. E’ stato dimostrato che gli esercizi di Kegel determinano un miglioramento in una forma di incontinenza da stress che varia da lieve a moderata nel 54% dei casi, con una regressione nel 16% dei casi [30,31]. E’ stato inoltre dimostrato che questi esercizi determinano un miglioramento dell’OAB [30,31]. Il Biofeedback, che aiuta le donne ad acquisire consapevolezza e controllo dei muscoli pelvici, e la stimolazione elettrica della muscolatura del pavimento pelvico possono essere impiegati per aumentare l’efficacia degli esercizi di Kegel. I coni vaginali rappresentano un altro metodo di rafforzamento dei muscoli del pavimento pelvico [29] e possono risultare utili nel trattamento dell’incontinenza da stress. Le tecniche di training della vescica, nelle quali al paziente viene insegnato a resistere allo stimolo di urinare e ad aumentare progressivamente l’intervallo tra gli svuotamenti, possono essere utilizzate con esito po-
However, compliance with bladder exercises and training is often poor [33].

**Pharmacotherapy**

Pharmacotherapy may be used in addition to or instead of behavioral techniques for the management of both stress and urge incontinence. It is possible that the a-adrenergic agonists, such as phenylpropanolamine, which increase tone in the proximal urethra, may help to reduce urine loss in women with stress incontinence [34, 35] but such therapy is rarely used because of concern over adverse events. Estrogen replacement therapy in combination with an a-adrenergic agonist have been shown to be effective in post-menopausal women with stress incontinence [34, 35] but again, because of concern over adverse events, these therapies are rarely used.

A number of different agents may be used to treat urge incontinence and OAB, including antimuscarinic drugs, such as tolterodine, oxybutynin, propantheline and hyoscyamine, the smooth muscle relaxant flavoxate and the tricyclic antidepressant imipramine. There is also evidence that estrogen replacement therapy can be beneficial in the management of OAB and mixed incontinence in some post-menopausal women [36] by alleviating symptoms of frequency, urgency, urge incontinence in women with stress incontinence by improving the urethral tone [34, 35]. However, estrogen replacement therapy is rarely used because of concerns over adverse events. A combination of estrogen and an a-adrenergic agonist has been shown to be effective in the management of stress incontinence in post-menopausal women [34, 35] and is used rarely because of concerns over adverse events. The addition of estrogen to a-adrenergic agonists has been shown to improve symptoms of urge incontinence in some post-menopausal women [36] and is used rarely because of concerns over adverse events. A number of different agents may be used to treat urge incontinence and OAB, including antimuscarinic drugs, such as tolterodine, oxybutynin, propantheline and hyoscyamine, the smooth muscle relaxant flavoxate and the tricyclic antidepressant imipramine. There is also evidence that estrogen replacement therapy can be beneficial in the management of OAB and mixed incontinence in some post-menopausal women [36] by alleviating symptoms of frequency, urgency, urge incontinence in women with stress incontinence by improving the urethral tone [34, 35]. However, estrogen replacement therapy is rarely used because of concerns over adverse events.

**Terapia farmacologica**

La terapia farmacologica può essere utilizzata in aggiunta o in sostituzione delle tecniche comportamentali per la gestione sia dell’incontinenza da stress che da urgenza. E’ possibile che gli agonisti alfa adrenergici, come ad esempio la fenilpropanolamina, che migliorano il tono nell’uretra prossimale, possano essere di aiuto nel ridurre la perdita di urina nelle donne con incontinenza da stress [34, 35], ma tale terapia viene utilizzata raramente a causa delle preoccupazioni destate dagli effetti collaterali. La terapia combinata che utilizza la supplementazione di estrogeni e un agonista alfa adrenergico ha evidenziato un’efficacia nelle donne in menopausa che soffrono di incontinenza da stress [34, 35], ma ancora, a causa delle preoccupazioni sugli effetti collaterali, queste terapie vengono utilizzate di rado.

E’ possibile utilizzare una serie di agenti diversi per il trattamento dell’incontinenza da urgenza e dell’OAB, inclusi i farmaci antimuscarinici, come ad esempio tolterodina, ossibutinina, propantelina e iosciamina, il flavossato rilassante della muscolatura liscia e l’imipramina antidepressivo triciclico. E’ anche dimostrato che la terapia estrogenica dia benefici nella gestione del fenomeno OAB e nell’incontinenza mi-
nence and nocturia [36]. Studies have shown that oxybutynin (Ditropan®), initially developed for its effects on the gastrointestinal system, lowers intravesical pressure, increases bladder capacity and reduces the frequency of bladder contractions [37]. However, its use is associated with profound antimuscarinic side effects, especially dry mouth and including, but not limited to, constipation and blurred vision. Discontinuation rates with oxybutynin may be as high as 60% [38]. Indeed, one study of treatment outcomes in women with OAB found that among those who received anticholinergic agents, of which oxybutynin was the most frequently prescribed (83.5% of patients), only 11.4% continued to take their medication for more than 6 months [38]. Furthermore, oxybutynin has been shown to cause cognitive impairment in elderly volunteers [39], which is of concern given the high prevalence of urinary incontinence among the elderly population. Oxybutynin is listed as potentially inappropriate for use in elderly patients [40]. An extended-release formulation of oxybutynin (Ditropan XL®) was developed in the hope that it would result in fewer incidences of dry mouth. However, a recent study [41] was unable to demonstrate any difference in efficacy or the mean dry mouth rate between the immediate-release and extended-release formulations of oxybutynin.

Tolterodine was developed specifically for use in OAB and may show benefits over other available agents. Tolterodine shows selectivity for muscarinic receptors in the bladder over sta in alcune donne entrate in meno-pausa [36] alleviando i sintomi di frequenza, urgenza, di incontinenza da urgenza e di nocturnia [36]. Gli studi hanno evidenziato che la ossibutinina (Ditropan®), sviluppata inizialmente per i suoi effetti sul sistema gastrointestinal, diminuisce la pressione intravesicale, aumenta la capacità della vescica e riduce la frequenza delle contrazioni della vescica [37]. Il suo utilizzo, tuttavia, viene associato a forti effetti collaterali legati all’antimuscarinico, specialmente la secchezza delle fauci e inclusi, ma non limitati ad essi, la costipazione e la vista annebbiata. Il tasso di discontinuità nel caso della ossibutinina può raggiungere livelli del 60% [38]. Infatti, uno studio sui risultati del trattamento nelle donne con problemi di OAB ha evidenziato che tra coloro i quali hanno ricevuto gli agenti anticolinergici, tra i quali l’ossibutinina è la più frequentemente prescritta (83.5% dei pazienti), soltanto l’11.4% ha continuato ad assumere la medicina per un periodo superiore a 6 mesi [38]. In aggiunta, è stato dimostrato che l’ossibutinina causa un peggioramento a livello cognitivo nei volontari anziani [39], cosa che risulta preoccupante se si considera l’alta diffusione dell’IU tra la popolazione anziana. L’ossibutinina viene elencata come potenzialmente inappropriata per l’utilizzo nei pazienti anziani [40]. Una preparazione a rilascio ritardato di ossibutinina (Ditropan XL®) è stata sviluppata nella speranza che possa avere come conseguenza una minore incidenza di effetti collaterali. Uno studio recente [41], tuttavia, non è stato capace di dimostrare alcuna differenza in efficacia o un’incidenza minore del fenomeno della secchez-
those in the salivary glands in both in vitro and in vivo studies [42]. Clinical studies have shown that tolterodine, 2 mg twice daily, is as effective as oxybutynin, 5 mg three times daily, in reducing the frequency of micturition and the number of incontinence episodes and in increasing the volume of urine voided per micturition [43, 44]. Typically, the mean daily micturition frequency was reduced by approximately 20% from baseline by both tolterodine and oxybutynin, and mean daily incontinence episodes were reduced by 40-60% by both treatments. However, the tolerability profile of tolterodine, and hence the potential for treatment compliance, is superior to that of oxybutynin [43, 44]. The percentage of patients reporting dry mouth as an adverse effect was significantly higher among patients receiving oxybutynin (up to 86%) compared with tolterodine-treated patients (almost 40%), as was the percentage of patients reporting moderate or severe dry mouth (up to 60% with oxybutynin compared with approximately 20% for tolterodine) [43, 44]. Consequently, the number of patients who withdrew from the studies because of this adverse effect was greater in the oxybutynin groups than in the tolterodine groups. The number of patient withdrawals from treatment with tolterodine has been shown to be similar to placebo (6% in placebo groups versus 5% in tolterodine group) [45]. A recent report [46] showed that the newly developed extended-release formulation of tolterodine demonstrated a statistically significant improvement in incontinence episodes and reduction in
dry mouth, compared with the immediate-release formulation of tolterodine.

Market assessment in 2000 showed that tolterodine is the most frequently prescribed product for OAB in the USA, exceeding both controlled-release and immediate-release formulations of oxybutynin. The assessment also showed that tolterodine is the most commonly prescribed molecule in the USA [47].

Surgery

**Stress incontinence**

Surgery is reserved for women with stress urinary incontinence who have failed to respond to behavioral therapy. Essentially, there are three approaches:

1. Injection therapy
2. Urethropexy
3. Sling procedures

**Injection therapy**

Genuine stress incontinence occurs...
because there is failure of the internal (bladder neck) and external urethral sphincter. The goal of injection therapy is to apply a bulking agent to the bladder neck to ‘reconstruct’ the internal sphincter. Many bulking agents have been tried and several are under development. Currently, the most commonly used is GAX (glutaraldehyde cross-linked) bovine collagen. As this is fairly expensive some surgeons have instead tried using endogenous fat but difficulty with harvesting and administering the fat limit its use. GAX collagen is indicated for the treatment of intrinsic sphincteric deficiency; for reimbursement, Medicare requires that the diagnosis be proven by documentation of a pre-procedure urethral leak point pressure of greater than 100 cmH₂O. Furthermore, practitioners are only allowed to use the GAX collagen technique after certification through the AUA.

**Urethropexy**

The main aim of suspension procedures to treat stress incontinence is to relocate the bladder neck within the intra-abdominal pressure zone and so optimize urethral sphincter function [48]. The techniques used include primarily anterior repair and the Burch colposuspension and in some cases the Marshall-Marchetti-Krantz procedure. Anterior repairs for stress incontinence tend to be carried out by generalists but are not favored by specialists given the high failure rate (about 50%) [49]. The Burch col-

*verifica a causa di un malfunzionamento dello sfintere uretrale (collo vescicale) interno ed esterno. L'obiettivo della terapia per iniezione è quello di applicare un agente che aggiunga volume al collo vescicale per “ricostruire” lo sfintere interno. Sono stati provati molti agenti che aggiungono volume e numerosi agenti sono in fase di sviluppo. Attualmente quello più frequentemente utilizzato è il collagene di origine bovina GAX (glutaraldeide a legami incrociati). Poiché si tratta di un prodotto estremamente costoso, alcuni chirurghi hanno tentato di utilizzare al suo posto il grasso endogeno ma la difficoltà riscontrata nel conservare e somministrare tale grasso limita il suo utilizzo. Il GAX è indicato per il trattamento dell’insufficienza intrinseca dello sfintere; per il rimborso, Medicare richiede che la diagnosi venga dimostrata da una documentazione che attesti una pressione uretrale, precedente alla chirurgia, maggiore di 100 cmH₂O. Inoltre l’utilizzo del GAX viene consentito ai medici soltanto dopo una certificazione acquisita tramite la AUA.*

**Uretropessi**

Lo scopo principale delle procedure di sospensione nel trattare l’incontinenza da stress è quello di riposizionare il collo vescicale all’interno della zona di pressione intra-addominale e, di conseguenza, ottimizzare la funzionalità dello sfintere uretrale [48]. Le tecniche utilizzate comprendono principalmente la riparazione anteriore, la colposospensione di Burch e, in alcuni casi, la procedura Marshall-Marchetti-Krantz. Le riparazioni anteriori per l’incontinenza da stress vengono tendenzialmente compiute da urologi o gine-
posuspension and the Marshall-Marchetti-Krantz procedure have both been reported to cure urinary incontinence in approximately 90% of women undergoing surgery for the first time, although the cure rate drops to approximately 80% if surgery has to be repeated [50]. Over the last decade, laparoscopic urethropexy has gained popularity because of the relatively reduced level of post-operative pain and length of hospital stay. While uncontrolled trials suggest that the cure rates for these minimally invasive procedures are similar to those for the open procedures, two randomized controlled studies have indicated that the open procedures are superior [51] [52].

Sling procedures

The pubo-vaginal sling procedure is popular among urologists as a primary procedure for stress incontinence as it has an equivalent success rate to the Burch colposuspension. However, it is associated with a higher risk of postoperative OAB and voiding difficulty [48]. Urogynaecologists tend to utilise the Burch colposuspension as the primary procedure as often this may be combined with a paravaginal repair for correction of a concomitant cystocele.

The last couple of years has seen the introduction of the tension-free vaginal tape (TVT) procedure which is inserted, often under local anes-
thetic, through the anterior wall of the vagina. A recent randomized controlled trial comparing TVT with Burch colposuspension demonstrated lower short-term morbidity and equivalent efficacy with TVT [53].

**Overactive bladder**

No surgical treatments have been advocated for continent OAB but one procedure which has been shown to be of some benefit for the treatment of urge incontinence is sacral nerve stimulation with an implantable stimulator [54]. Further trials with this device need to be performed before it can be advocated for widespread usage. The surgical treatment of last resort for urge incontinence is augmentation cystoplasty, in which the capacity of the bladder is increased so that contractions of the bladder during the filling phase do not result in leakage of urine. Cystoplasty may involve either the incorporation of a portion of bowel into the dome of the bladder (a procedure known as enterocystoplasty) or excision of a large portion of detrusor muscle with preservation of the underlying mucosa to allow development of a diverticulum (a procedure known as auto-augmentation) [55]. Although enterocystoplasty is effective, complications may include inadequate voiding, retention of mucus and electrolyte imbalance. Auto-augmentation avoids the post-operative morbidity that may develop following enterocystoplasty, but it is not considered to be as effective [9].

**Iperattività vescicale (OAB)**

Nessun trattamento chirurgico è stato patrocinato per il fenomeno di OAB continent, ma una procedura che è stata indicata essere di qualche beneficio per il trattamento dell’incontinenza da urgenza è la stimolazione del nervo sacrale con uno stimolatore implantabile [54]. Ulteriori esperimenti con questo dispositivo devono ancora essere eseguiti prima che ne venga patrocinato un utilizzo più diffuso. Come ultima risorsa, il trattamento chirurgico per l’incontinenza da urgenza è la cistoplastica per ampliamento, nella quale si aumenta la capacità della vescica in modo tale che le contrazioni vesicali durante la fase di riempimento non determinino una perdita di urina. La cistoplastica può richiedere o l’incorporamento di una porzione di intestino nella vescica (una procedura nota come enterocistoplastica) o l’asportazione di una larga porzione del muscolo detrusore preservando la mucosa sottostante per consentire lo sviluppo di un diverticolo (una procedura nota come autoampliamento) [55]. Sebbene l’enterocistoplastica sia efficace, esistono complicazioni che possono comprendere uno svuotamento inadeguato, la ritenzione di muco e uno squilibrio elettrolitico. L’autoampliamento evita la morbidità post operatoria che
The costs associated with urinary incontinence and OAB are high. For example, it is estimated that $1.1 billion is spent each year in the USA on disposable pads for adults [28]. In addition, there may be difficulties in obtaining reimbursement for certain behavioural therapies. A 1995 study of the economic impact of incontinence in individuals aged 65 years of age and older in the USA estimated the societal cost to be $26.3 billion, or $3565 per patient [56]. The direct costs alone, including diagnostic and treatment costs, routine care, and consequence costs, were estimated to represent $25.6 billion of the total costs – greatly exceeding the $14 billion.
lion in direct medical costs spent on treatment of osteoporosis, for example [57]. The cost of care for urinary incontinence and OAB is rising; estimates have increased from $8.2 billion in 1984 to $16.4 billion in 1993 to the current published estimate of $26.3 billion. This observed increase may be partly attributed to the aging population, but also in the number of comorbid events associated with under-treatment. In the NOBLE Program, a cost-of-illness analysis is also under way to identify the OAB-specific burden, in addition to the costs associated with UI.

The direct costs associated with urinary incontinence include the costs of diagnosis and of treatment, including behavioral techniques, pharmacotherapy and surgery, as well as costs arising from management of the consequences of urinary incontinence, such as skin irritation, urinary guenye, sono stati stimati in $25.6 miliardi dei costi totali – superando di gran lunga i $14 miliardi in costi medi-diretti spesi nel trattamento delle osteoporosi, ad esempio [57]. Il costo della cura nei casi di incontinenza urinaria o di OAB è in crescita; le stime sono aumentate da $8.2 miliardi nel 1984 ai $16.4 miliardi nel 1993, fino al-la stima recentemente pubblicata che si attesta a $26.3 miliardi. Questo au-mento riconosciuto può essere in parte attribuito all’invecchiamento della po-polazione. Anche nel Programma NO-BLE, un’analisi dei costi della malattia è in fase di sviluppo per l’identificazio-ne dell’onere specifico per l’OAB, in aggiunta ai costi associati all’incon-tinenza urinaria (UI).

I costi diretti associati all’IU comprendono i costi della diagnosi e del trattamento, incluse le tecniche comportamentali, la terapia farmacologica e la chirurgia come pure i costi deri-
tract infections and falls as a result of patients rushing to reach the toilet [56]. The indirect costs include costs associated with home care, such as loss of earnings by either the patient or her partner, and laundry costs as a result of incontinence episodes.

As Wagner and Hu point out, the figure of $26.3 billion annually is almost certainly an underestimate of the true costs of urinary incontinence in the USA, as it does not include costs for patients under 65 years of age [56]. While the costs of diagnosis and treatment among such patients would be unlikely to differ from those of older patients, they might be expected to have higher indirect costs due to loss of earnings. Indeed, based on an estimated prevalence of 14 million, Hu and Wagner calculated that the total costs of urinary incontinence could be as high as $46 billion annually [56].

Figure 4c - Distribution of consequences costs [56].
CONCLUSION

Urinary incontinence and OAB continue to be ‘silent diseases’ and have been referred to as “one of the last social taboos” [23]. They are associated with considerable economic impact and significant reductions in HRQoL.

Urinary incontinence is estimated to affect approximately 13 million people in the USA, and is seen more commonly in women than in men. However, variability between studies in the population investigated and in the definition of urinary incontinence has made it difficult to obtain accurate estimates of the prevalence of urinary incontinence in women. Furthermore, many epidemiological studies have focused only on urine loss without consideration of symptoms of urinary frequency and urgency. Consequently the true prevalence of the symptoms of frequency and urgency with or without urge incontinence (OAB) is unknown, although is estimated to be at least 17 million people in the USA.

Little is known about the natural history of incontinence or OAB. There is evidence of remission in some patients (i.e. previously incontinent patients become continent over time), although the estimated remission rates vary widely [58-60]. Clearly, this is an area for further study. It is hoped that

della perdita di guadagni. Infatti, in base a una diffusione stimata di 14 milioni di dollari, Hu e Wagner hanno calcolato che i costi totali dell’incontinenza urinaria potrebbero aggirarsi sui $46 miliardi annuali [56].

CONCLUSIONE

L’incontinenza urinaria e il fenomeno di OAB continuano ad essere “malattie silenziose” a cui è stato fatto riferimento come “uno degli ultimi tabeo sociali” [23]. Esse vengono associate a un impatto economico considerevole e a una riduzione significativa nella HRQoL.

Si stima che l’IU affligga circa 13 milioni di persone negli USA e si verifichino più frequentemente nelle donne piuttosto che negli uomini. Tuttavia la variabilità tra gli studi effettuati nella popolazione analizzata e nella definizione di incontinenza urinaria ha reso difficile ottenere stime accurate della diffusione dell’incontinenza urinaria nelle donne. Inoltre, numerosi studi epidemiologici si sono concentrati soltanto sulla perdita di urina tralasciando i sintomi di urgenza e frequenza urinaria. Di conseguenza la reale diffusione dei sintomi di frequenza e urgenza associati o meno all’incontinenza da urgenza (OAB) è sconosciuta, sebbene si stima che sia almeno pari a 17 milioni di persone negli Stati Uniti d’America.

La conoscenza dell’evolversi naturale dell’incontinenza o dell’OAB è scarsa. Esistono testimonianze di regressione in alcuni pazienti (i.e. pazienti precedentemente incontinenti sono diventati continenti col tempo), sebbene i tassi di regressione stimati variano ampiamente [58-60]. Chiaramente si tratta
the NOBLE (National Overactive Bladder Evaluation) Program will provide a more accurate picture of the prevalence, impact, burden and natural history of OAB in the USA.

A range of effective treatments are available for the patient with urinary incontinence or OAB. Behavioral techniques, such as Kegel exercises for urinary incontinence and bladder retraining techniques for urge incontinence and OAB are effective in reducing incontinence episodes in many patients. Surgery is effective in up to 90% of women with stress incontinence and the Sling and Burch colposuspension are the most popular. Pharmacotherapy, particularly treatment with anticholinergic agents, is used for the treatment of urge incontinence and OAB. The antimuscarinic agent oxybutynin is associated with a high incidence of adverse effects, particularly dry mouth. Tolterodine, a new antimuscarinic agent that has been developed specifically for the treatment of OAB, is as effective as oxybutynin but has a superior tolerability profile and is the most commonly used agent [47].

Finally, education of both healthcare professionals and the public is the key to the optimal management of urinary incontinence. Public education is required to remove the stigma surrounding urinary incontinence and to empower patients and their families to obtain the most appropriate treatment and support. Classification of OAB as a disease will raise the profile of bladder symptoms among healthcare professionals and encourage them to maintain clinical suspicion, and to correctly diagnose
and manage cases in a timely manner.

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