

Bethanechol Remains the Preferred Drug in Suspected Underactive Bladder: Findings from Nation-Wide Prescription Analysis

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Abstract

Background: Bethanechol chloride, a cholinergic agonist, is often prescribed in suspected underactive bladders to improve detrusor contractility, despite its limited clinical efficacy. We investigated the usage pattern of bethanechol in actual practice with the understanding that it would enable the physicians to make an informed decision on the coherent use of bethanechol. **Methods:** A nation-wide survey was carried out to obtain the responses of the urologists. Out of the 755 urologists approached, 630 survey responses were considered for analysis. **Results:** Usage of bethanechol was advocated as very common [318 (50.48%)], common [200 (31.75%)], not so common [107 (16.98%)], and rare [5 (0.79%)] in postoperative urinary retention, where it was preferred either exclusively [255 (40.48%)] or along with alpha blockers [247 (39.21%)]. Predilection to use alpha-blocker [247 (39.21%)], alpha-blocker plus naloxone [4 (0.64%)], naloxone [1 (0.16%)], alpha-blocker plus bethanechol plus naloxone [1 (0.16%)] was also observed. It was also preferred individually in pathologies causing urinary retention such as benign prostatic hyperplasia [125 (19.84%)], diabetic neuropathy [82 (13.02%)], neurological diseases [69 (10.95%)], senile bladder [14 (2.22%)], drugs [13 (2.06%)], and infective/inflammatory conditions [6 (0.95%)]. Other [321 (50.95%)] physicians opted to prescribe bethanechol in two or more of the enumerated indications. Bethanechol was prescribed orally as 25 mg thrice daily [441 (70.00%)], 50 mg thrice daily [86 (13.65%)], 25 mg four times daily [59 (9.37%)], and many “strongly agree” and “agree” that its sustained release formulation may offer better treatment compliance [565 (89.68%)], safety [548 (86.99%)], and efficacy [544 (86.35%)]. **Conclusion:** Bethanechol was the most prescribed drug for the management of postoperative urinary retention and other pathologies suspected to cause underactive bladder.

Keywords

Bethanechol, Benign Prostatic Hyperplasia, Detrusor Underactivity, Urinary Retention, Underactive Bladder

1. Background

Underactive bladder (UAB) or detrusor underactivity (DU) is a challenging condition that affects 45% of men and women over 70 years of age [1]. Its management revolves around the primary objective to relieve voiding difficulty, reduce postvoid residual urine, and urinary tract infection. Clean intermittent catheterization (CIC) is the standard of care and the recommended treatment option; however, CIC has its own limitations that include urethral strictures, urethral false passages, hematuria, bacteriuria, and labial erosion [2]. CIC and indwelling catheters have also been shown to reduce the quality of life of patients and cause emotional stress [3].

Pharmacological management of UAB is aimed at increasing intravesical pressure and detrusor contractility while decreasing bladder outlet resistance. Bethanechol is a cholinergic agonist that induces contraction of the detrusor muscle. It has demonstrated efficacy in a selected group of patients [4] [5]. However, the doses required to obtain the desired therapeutic responses in UAB are quite high and may cause systemic side effects. Therefore, bethanechol is often preferred later in the therapy and is not recommended as the first line [6].

In spite of this, health care professionals continue to prescribe bethanechol, as observed in the recent study by Gaitonde S, *et al.* [6]. This study demonstrated that bethanechol was prescribed in patients with atony of bladder, urinary retention, neurogenic bladder, urinary incontinence, and incomplete bladder emptying. Although this study reported the primary diagnosis, it could not provide details about the actual patients' diagnosis due to the retrospective nature of the study. Further exploration of additional parameters like the preferred indications, dosages, advantages of improved drug delivery systems (sustained release formulations) in terms of safety, efficacy and compliance may help health care professionals (HCPs) to take an informed decision to use bethanechol whose efficacy is much debated.

Urologists constitute the major population (more than 90%) amongst the HCPs to prescribe bethanechol [6], and hence we performed a nation-wide survey of the urologists to assess the prescription pattern of bethanechol in actual clinical practice.

2. Methods

Bethanechol is prescribed by health care providers to improve detrusor contractility due to limited treatment options to manage pathologies associated with underactive bladder. Market survey data also revealed that the usage (sale) of

bethanechol was quite high, despite studies demonstrating its limited efficacy. Similarly, evidence on the prescription pattern of bethanechol is limited to one retrospective study that provides only the primary (syndromic) diagnosis of patients prescribed bethanechol. This questionnaire-based feedback survey was designed with the objective of exploring into more details about the prescription pattern of bethanechol in actual practice. The information is expected to escort the HCPs to adapt a balanced approach to use bethanechol in the most appropriate manner considering its safety and efficacy.

A survey was conducted across the country in 14 states (5 North, 4 South, 3 East, and 2 West). Out of the approximate 4200 urologists in the country, a total of 755 HCPs (urologists) were approached, out of whom 630 completed the survey. HCPs had the option to attempt the survey either online or offline on a physical form. Survey forms were designed to capture details about the preferred indications and dosages of bethanechol, and the perceived advantages of improved drug delivery systems (sustained release tablets of bethanechol) in terms of compliance, safety, and efficacy. The survey form also captured the personal details of the HCPs, such as name, specialization, and place of practice. Data was entered in Microsoft Excel 2019 for analysis and compiled into pivot tables. Charts and graphs were prepared from the compiled data.

3. Results

A total of 755 HCPs took part in the survey, out of which 630 completed it. The survey population included 92 (14.60%), 197 (31.27%), 169 (26.83%), and 172 (27.30%) HCPs from east, west, north, and south of India, respectively. Responses were obtained online and on physical survey forms from 490 (77.78%) and 140 (22.22%) HCPs, respectively.

It was observed that 318 (50.48%), 200 (31.75%), 107 (16.98%), and 5 (0.79%) HCPs reported usage of bethanechol as common, very common, not so common, and rare, respectively, for the management of postoperative urinary retention (**Table 1**). Similarly, 255 (40.48%), 247 (39.21%), 122 (19.37%), 4 (0.64%), 1 (0.16%), 1 (0.16%) HCPs preferred muscarinic agonists (bethanechol), alpha-blocker, alpha-blocker plus muscarinic agonists (bethanechol), alpha-blocker plus naloxone, naloxone, alpha-blocker plus muscarinic agonists (bethanechol) plus naloxone, respectively, for management of postoperative urinary retention (**Table 1**).

Bethanechol was also exclusively preferred in BPH, diabetic neuropathy, neurological diseases because of lower motor neuron lesions, senile bladder, underactive bladder due to infective/inflammatory causes, underactive bladder due to drug usage by 125 (19.84%), 82 (13.02%), 69 (10.95 %), 14 (2.22 %), 13 (2.06 %), 6 (0.95 %) HCPs respectively (**Table 2**). While the other 321 (50.95%) HCPs opted to prescribe bethanechol in two or more of the enumerated indications.

In practice, 25 mg per oral (PO) three times daily, 50 mg PO three times daily, 25 mg PO four times daily, were the commonly preferred dosages by 441 (70.00%),

Table 1. Usage of bethanechol in post operative urinary retention (POUR) and preferred drugs in the indication.

	Responses (n = 630)	
	No. of doctors	Percentage
Bethanechol usage in POUR		
Common	318	50.48
Very common	200	31.75
Not so common	107	16.98
Rare	5	0.79
Preferred drugs in POUR		
Muscarinic agonists (bethanechol)	255	40.48
Alpha-blocker	247	39.21
Alpha-blocker + Muscarinic agonists (bethanechol)	122	19.37
Alpha-blocker + Naloxone	4	0.63
Naloxone	1	0.16
Alpha-blocker + Muscarinic agonists (bethanechol) + Naloxone	1	0.16

Table 2. Usage of bethanechol in other clinical conditions.

Preferred Indications	Responses (n = 630)	
	No. of doctors	Percentage
Benign prostatic hyperplasia	125	19.84
Diabetic neuropathy	82	13.02
Neurological diseases (lower motor neuron lesions)	69	10.95
Underactive bladder due to senile bladder changes	14	2.22
Underactive bladder due to infective/inflammatory causes	13	2.06
Underactive bladder due to drug usage	6	0.95
Two and more of the above enumerated indications	321	50.95

86 (13.65%), and 59 (9.37%) HCPs, respectively (**Table 3**). Few HCPs initiated bethanechol at 25 mg PO three times daily and then preferred to either up-titrate [8 (1.27%)], down titrate [2 (0.32%)], or use a sustained release formulation [9 (1.43%)] of bethanechol 75 mg tablet. Other HCPs preferred dosages of 10 mg PO three times daily [9 (1.43%)], 10 mg PO four times daily [1 (0.16%)], 25 mg PO two times daily [7 (1.11%)], and 50 mg PO two times daily [6 (0.95%)]. While few others preferred to initiate with 25 mg PO two times daily, followed by 50 mg PO two times daily [1 (0.16%)], 50 mg PO three times daily, followed by 50 mg PO two times daily [1 (0.16%)].

Table 3. Preferred dosages of bethanechol.

Preferred dosage	Responses (n = 630)	
	No. of doctors	Percentage
25 mg PO three times daily	441	70
50 mg PO three times daily	86	13.65
25 mg PO four times daily	59	9.37
25 mg PO three times daily 75 mg SR once daily	9	1.43
10 mg PO three times daily	9	1.43
25 mg PO three times daily 25 mg PO four times daily or 50 mg PO three times daily	8	1.27
25 mg PO two times daily	7	1.11
50 mg PO two times daily	6	0.95
25 mg PO three times daily 25 mg PO two times daily	2	0.32
10 mg PO four times daily	1	0.16
25 mg PO two times daily 50 mg PO two times daily	1	0.16
50 mg PO three times daily 50 mg PO twice times daily	1	0.16

It was observed that 565 (89.68%), 548 (86.99%) and 544 (86.35%) HCPs strongly agree and agree that the sustained release formulation of bethanechol 75 mg oral tablet may offer advantage to the patients in terms of better treatment compliance, safety and efficacy respectively due to less fluctuations of the drug levels in the blood, while other 65 (10.32%), 82 (13.02%) and 86 (13.65%) HCPs somewhat agree and do not agree to this postulation (**Figure 1**).

Common adverse effects like diarrhea, abdominal pain, headache, nausea, dry mouth was reported 42 (6.67%), 25 (3.97%), 20 (3.17%), 19 (3.02%), 15 (2.38%) times, respectively, as the associated side effects with bethanechol use (**Table 4**). While no side effects were reported 445 (70.63%) times in the survey.

4. Discussion

This survey assessed the prescription pattern of bethanechol amongst the urologists in the Indian clinical setup. It was observed that the maximum HCPs reported usage of bethanechol for management of post-operative retention of urine (POUR), which is in line with its approved indication. They preferred bethanechol, either alone or in combination with other drugs, to manage POUR. Alpha-blockers were seen to be commonly preferred either alone or along with bethanechol. The use of alpha blockers can be explained by their inhibitory action on the elevated sympathetic activity that may inhibit the micturition reflex

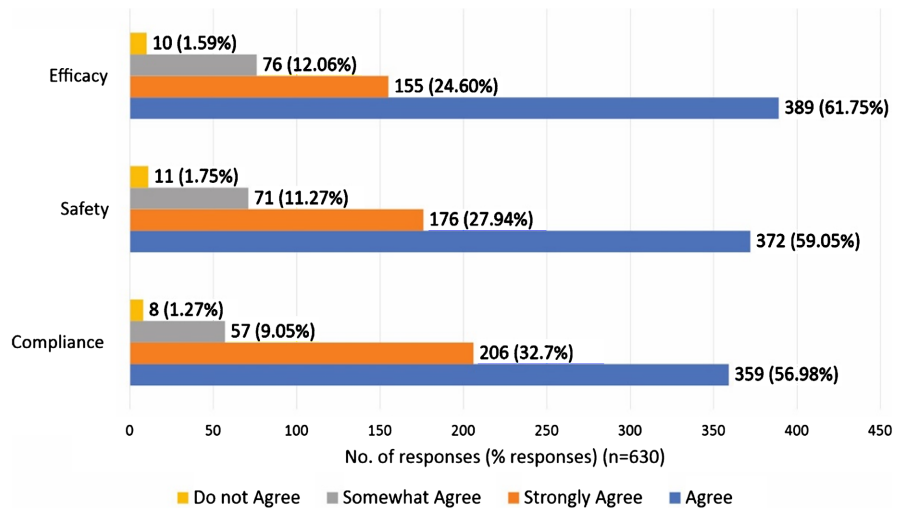


Figure 1. Perceived advantage of bethanechol 75 mg sustained release tablet in terms of compliance, safety, and efficacy.

Table 4. Side effects reported with bethanechol.

Side effects	Number of times which the side effects were reported due to the drug (% of times) (n = 630)
No side effects	445 (70.63)
Diarrhea	42 (6.67)
Abdominal pain	25 (3.97)
Headache	20 (3.17)
Nausea	19 (3.02)
Dry mouth	15 (2.38)
OAB symptoms, urine frequency/leak, urgency	10 (1.59)
Vomiting	8 (1.27)
Dizziness	7 (1.11)
Sweating	7 (1.11)
Acidity, acute gastritis, belching, bloating, constipation, fullness of abdomen	6 (0.95)
Excessive salivation	6 (0.95)
Neurological complaints	4 (0.63)
Retention of urine	4 (0.63)
Extrapyramidal symptoms-palpitation and tremors	3 (0.48)
Itching	2 (0.32)
Worsening of LUTS	2 (0.32)
Breathlessness	1 (0.16)
Increased BP	1 (0.16)

Continued

Myalgia	1 (0.16)
Tolerance with long term use	1 (0.16)
Unresponsive to symptoms	1 (0.16)

after the surgery [7]. Indeed, it has been reported in the study by Gill S, *et al.*, that the incidence of POUR was lower in patients administered alpha blockers prophylactically, and hence they highly recommend them for patients operated under general anesthesia [8]. The combination of alpha-blocker plus bethanechol is in line with the findings from the study by Yamanishi T, *et al.*, which demonstrated combination therapy with a cholinergic drug and α -blocker to be more useful than monotherapy alone for the treatment of underactive detrusor [9], although this study did not include patients posted for surgery. Naloxone was also reported to be used either alone or in combination with other drugs to manage POUR. Naloxone is an opioid antagonist that may ameliorate the urinary retention caused by usage of opioids post-operatively [10]. However, it may antagonize analgesia in postoperative patients, which may limit its usage.

Bethanechol is presently approved for the treatment of acute postoperative and postpartum nonobstructive (functional) urinary retention and for neurogenic atony of the urinary bladder with retention [11]. In this survey, bethanechol was prescribed for various conditions like benign prostatic hyperplasia, diabetic neuropathy, underactive bladder because of infective or inflammatory causes, retention of urine due to drugs, neurological conditions such as lower motor neuron lesions causing urine retention, and senile bladder.

It was observed that many HCPs preferred bethanechol in benign prostatic hyperplasia (BPH). These observations differ from the general guidance in which alpha-blockers, 5-alpha-reductase inhibitors, and their combinations are generally recommended to address lower urinary tract symptoms (LUTS) from BPH. The mechanism attributed to cause detrusor underactivity in bladder outlet obstruction (BOO) is possibly due to the accumulation of collagen within the detrusor muscle as the bladder undergoes morphological and functional remodeling [12]. Indeed, urodynamic studies have demonstrated DU in 11% to 40% of patients with LUTS/BPH [13]. However, it is often difficult to attribute the cause of the reduced flow rate to either DU or BOO, and hence it is recommended to diagnose DU by performing a urodynamic study with a pressure flow study.

Preference for bethanechol in diabetic neuropathy was reported by many HCPs in the survey. Detrusor underactivity may manifest in diabetes patients because of the damage to the visceral afferent fibers in the bladder wall due to long-standing postvoiding residual volumes and enhanced bladder capacity caused by decreased bladder sensation and contraction [14] [15]. Indeed, 23% of diabetic cystopathy patients have been reported to exhibit reduced detrusor contractility [16]. However, bladder hypersensitivity and hypercontractility were

found to be more common than an underactive bladder in the study [15]. Literature search, reports a case study in an 86-year-old diabetic man successfully treated with bethanechol for diabetic visceral neuropathy [17].

The preference of bethanechol in neurological conditions due to lower motor neuron lesions is in line with the recommended indication of bethanechol in neurogenic atony of the bladder. Multiple case studies have also demonstrated the efficacy of bethanechol in neurogenic bladder [4].

Few HCPs also preferred bethanechol in senile bladder. Senile or aging bladders often manifest as detrusor overactivity, impaired contractility, or a combination of both [18] [19]. Voiding dysfunctions in the elderly could be attributed to various mechanisms such as detrusor fibrosis and impaired contractility [20], collagen deposition [21], and loss of acetylcholinesterase-positive nerve terminals [22]. Madersbacher S., demonstrated that older patients of both sexes had higher residual urine volumes [23]. Similarly, aging men demonstrated comparable age-associated urodynamic changes to those of women, suggesting a non-sex-specific aging process of the urinary bladder [23]. However, very little data exists about the usage of bethanechol in senile bladder, that needs to be further investigated.

Usage of bethanechol in underactive bladder due to infective or inflammatory causes may be due to the fact that infectious neurological problems (infections affecting the nervous system) are one of the causes of underactive bladder [24]. Fudaba H., reports a case study of cerebral malakoplakia where bethanechol improved the bladder symptoms [25].

Preferred dosages of bethanechol in adult patients were in line with the recommended doses, which ranged from 10 to 50 mg three or four times a day [11]. Most HCPs concur that a sustained-release formulation of bethanechol 75 mg oral tablet may offer advantages in terms of better compliance, safety, and efficacy due to less fluctuation of the drug levels in the blood; this hypothesis, however, needs to be further investigated in a randomized clinical trial. The side effects reported by the HCPs in the survey are in line with the prescribing information of bethanechol.

5. Limitations

The data collected in this survey is at a single point and may vary with time as new advances evolve in the therapy to manage DU. Even though efforts are being made to collect the data from a larger geographical region, the observations mentioned in this survey may not represent the whole population of the country. The efficacy of bethanechol in the indications preferred over and above the approved indications represents only the opinion of the HCPs and needs to be confirmed in randomized clinical trials.

6. Conclusion

Bethanechol thus remains the drug of choice among the HCPs and is commonly

preferred in patients with suspected detrusor underactivity. This preference is over and above the actual recommended indications. It is prescribed within the recommended dosing regimen to achieve a balance between its efficacy and toxic effects. HCPs also believed that the sustained release formulation of bethanechol may help to achieve a better response in terms of safety, efficacy and treatment compliance.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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List of Abbreviations

UAB: underactive bladder;
DU: detrusor underactivity;
CIC: clean intermittent catheterization;
PO: per oral;
POUR: post-operative retention of urine;
BPH: benign prostatic hyperplasia;
LUTS: lower urinary tract symptoms;
HCPs: health care professionals;
BOO: bladder outlet obstruction.