

Effect of Designed Nursing Instructions on Outcomes of Patients with Overactive Bladder Syndrome Undergoing Intravesical Botox Injection

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Abstract

Background: Botox is a new form of treatment for over active bladder syndrome and is administered via cystoscopic injections of the bladder wall. **Aim:** To evaluate the effect of nursing instructions on outcomes of patients with overactive bladder syndrome undergoing intravesical botox injection. **Research design:** Quasi-experimental design was utilized. **Setting** the study was conducted in the urology departments at Assiut Urology University Hospital. **Sample:** Purposive sample of thirty patients undergoing intravesical botox injection. This sample was divided into study and control groups (15 patients for each). **Tools: tool (I):** Patient structured interview questionnaire sheet. **Tool (II):** Numeric scale for pain. **Results:** there was significant difference between study and control group after application of nursing instructions regarding total knowledge. In study group one fifth of patients had recurrence of urinary incontinence post application of nursing instructions while in control group more than half (60%). the mean score of numeric scale for assessment of pain was 1.2 ± 0.68 in study group while in control group was 3.4 ± 1.76 post instructions. **Conclusion:** Nursing instructions are effective in improves patient's outcomes for the study sample. **Recommendations:** Kegel exercises can be adapted as therapeutic behavioral methods for care of patients with overactive bladder syndrome for patients undergoing intravesical botox injection

Keywords: *Nursing Instructions, Intravesical Botox Injection/& Overactive Bladder.*

Introduction

Botox is a neurotoxic protein produced by the Clostridium Botulinum bacterium and its associated organisms. This prevents the release of the neurotransmitter acetylcholine at the neuromuscular junction from axon ends. (Farag et al., 2020)

Botox has been commonly used to treat a variety of bladder disorders including muscle spasms and the overactive bladder. Also a botox injection is a treatment used to treat extreme symptoms of bladder; such as intense pain, inability to delay urination and urge sphincter spasm. (Vinay et al., 2008)

Botox injections are used in patients with non-surgical treatment options which failed. Bladder injections are done via a cystoscope inserted into the urethra. The operation takes about 15 minutes and can be done under general anesthesia, sedation or local anesthesia as a day surgery. (Chung, 2017) Botox effect is temporary; bladder injection lasts around 9 months. Some patients cannot respond to the therapy. It may take 2-4 days to work and can take up to 7 days to reach full impact (Abrams et al., 2019).

Overactive bladder is a syndrome consisting of any one of four key symptoms; urinary urgency, urge incontinence, urinary frequency, and nocturia. It has a detrimental effect on the life of a person. The need to

urinate regularly may occur during daytime, at night or both. When the bladder control is compromised then it is known as urge incontinence. More than 40 per cent of overactive bladder patients have incontinence. Conversely, about 40% to 70% of urinary incontinence is due to overactive bladder. (Gormley et al., 2015).

Urinary incontinence is characterized as any involuntary urinary loss that causes a person to experience asocial or hygienic problems. It is estimated that between 30% - 40% of middle-aged women have some form of incontinence and this number rises with age. (Joseph et al., 2019)

Stress incontinence is the excessive urinary loss associated with physical exertion that induces increased abdominal pressure (such as crying, laughing, running or walking). Urge incontinence (overactive bladder) happens when the muscles of the bladder begin to contract, and urine is expelled. Such contractions may cause a sudden, intense urinary urge, the main symptoms are: the need to urinate frequently and the need to pass urine during the night. Mixed urinary incontinence is calculated that 30% of women with incontinence suffer from both types. (Gibbs & Ronald 2016)

Nursing instructions before botox injection include; check that the patient avoids all blood thinner for (5) days before the operation; make urine culture and take antibiotics as prescribed. Often, nurses advise the patient to prepare for fasting before the operation by consuming a light meal the day before the procedure and fasting for 8 hours. (Osman et al., 2018)

Nursing instructions after the procedure including the following; the patient drinks plenty of fluids after the operation to help prevent bleeding and pain. Taking a warm bath or placing a warm moist compress, wet washcloth over the opening of the urethral often helps to alleviate any discomfort. If the patient complains any of the following symptoms, the patient should call the physician: urination issues, serious bleeding, and fever, chills, confusion, disorientation, agitation, severe abdominal pain, or any other unusual reaction. (Aditya & Pradhan 2018)

Also the patient instructed following an intravesical botox procedure mostly involves methods of prevents urinary tract infection. Most people can continue with normal daily activities immediately after the procedure, although they may be affected by some pain in the first 24-48 hours. (Blankstein et al., 2016).

The nurse also instructs the patient on the value of pelvic floor exercise and bladder preparation. Pelvic floor exercises also called kegel exercises are an easy way to help develop strength in pelvic floor muscles, and can help control urge incontinence and discomfort, more control with stronger pelvic floor muscles. Patients with weak pelvic floor muscles if leak urine or feces when laugh, run, cough, lift something should do these exercises. And instructs the patient to use some therapeutic behavioral methods are initially recommended. As weight loss in those patient who are overweight, decreasing caffeine consumption, and drinking moderate fluids, can also have benefits. (Gormley et al., 2012)

Significance of the study

Intravesical botox is safe procedure has been commonly used to treat a variety of overactive bladder syndrome recently. Overactive bladder disorders are a common symptom that can affect patients of all ages. This study is the first in our district which provides those patients with instructions about botox injection pre, during and post-operative. So, we sought to attempt to establish a nursing instruction to improve the urinary incontinence symptoms and help patients return to normal pattern of daily living activities.

Operational definition

- Intravesical botox is a procedure that involves an injection of botulinum type A toxin in to the

muscles of the bladder wall. The toxin produced by clostridium botulinum binds to the nerves endings and inhibits the muscular contractions.

- Nursing instructions: It refers to the advices or teaching and guidance that are provided by the professional nurse and must be followed by the patient regarding improving knowledge, and minimizes pain level and recurrence of urinary incontinence for patients undergoing intravesical botox injection.
- Patients' outcomes: measurement based on comparisons between both groups (study & control) regarding outcomes measures which include the patient's knowledge, recurrence of urinary incontinence and pain control

Aim of the study

The aims of this study were to;

1. Assess knowledge for patients with overactive bladder syndrome undergoing intravesical botox injection
2. Design and implement nursing instructions for patients with overactive bladder syndrome undergoing intravesical botox injection
3. Evaluate the effect of nursing instructions on outcomes (improve knowledge, minimize pain level and recurrence of urinary incontinence) for patients undergoing intravesical botox injection.

Research hypothesis

To fulfill the aims of the study the following research hypotheses were formulated:-

1. The mean knowledge scores among patients in the study group who exposed to the nursing instructions will be higher than those in the control group.
2. The incidence of pain level after application of nursing instructions among patients in the study group will be less than those in the control group.
3. Recurrence of urinary incontinence after application of nursing instructions among patients in the study group will be less than those in the control group.

Patients & Methods

Research design

Quasi-experimental study design was utilized.

Technical design

Setting

The study was conducted in the urology departments at Assiut Urology University Hospital.

Sample

Purposive sample of thirty patients who were admitted to the urology departments and urology outpatient clinic at Assiut Urology University Hospital and undergoing intravesical botox injection. This sample was divided randomly into two equal groups; study and control groups (15 patients each).

The study group who received nursing instructions and control group received routine hospital care.

Inclusion Criteria

1. Age ranges between 20 – 65 years
2. Both sexes (male and female)
3. Patients who have proven Over Active Bladder (OAB) on urodynamic investigation. Have been unresponsive to other treatments, and have severe symptoms such as frequency, urgency and urinary incontinence.

Exclusion criteria

1. Patient with urinary tract infection.
2. Positive urinary culture

Sample size

The power analysis to estimate the sample size was performed based on the result of previous study. Assuming power of 0.05% and 0.20 (one sided equivalence test). A total sample size of 28 participants is required. The eligible patients were invited to participate after the assessment, they meet all of the inclusion criteria $n = 30$

Tools for data collection

Two tools were utilized in this study:

Tool (1): Patient structured interview questionnaire sheet: It developed by the researchers and divided into four parts

Part one: Demographic data: it included patient's age, gender, residence and marital status, level of education, occupation

Part two: Medical data: It included duration of disease, urge symptoms such as, urgency, dysuria, urge sphincter spasm, nervous bladder, urinary incontinence.

Part three: Assessment of patients' knowledge: To assess patients' knowledge as regarding to intravesical botox injection. It consisted of four sections.

Section (1): It contained 5 questions used to assess patient's level of knowledge as regard to: intravesical botox information such as definition, benefits, risks of botox injection...etc.

Section (2): It contained 4 questions used to assess patient's level of knowledge as regard to tests and investigations conducted before procedure, current medications, informed consent, instructions before treatment

Section (3): It contained 6 questions used to assess patient level of knowledge as regard the instructions that were given during the operation such as the type of anesthesia used, the duration of the operation, patient's position during the operation, How many times of injection.

Section (4): It contained 4 questions used to assess patient level of knowledge as regard instructions that were given after the procedure such as what happens after the procedure, what are the prescribed

medications, what are post procedure precautions, and follow-up appointment.

Scoring system: The total score of questionnaires was 19 degree for each of the knowledge items, a correct response scored as (1) and the incorrect (zero) This system translated in results into satisfactory and unsatisfactory, satisfactory includes answers that are completely correct. & unsatisfactory includes answers as don't known, wrong, & incompletely correct. Scores more than 60 % were graded as satisfactory level of knowledge. Scores less than 60 % were graded as unsatisfactory level of knowledge.

Part four: recurrence of urinary incontinence post nursing instructions: it involved the number of recurrence of urinary incontinence through 6 months after intravesical botox injection.

Tool (II): Numeric Scale for pain

It was adopted from **Flaherty. (1996)** and used by the researchers to assess pain for patients undergoing botox injection. The scale determines the level of pain intensity was scaled as follows: (0) no pain, (1- 3) mild pain degree, (3-5) moderate pain and (6-10) sever pain degree.

Designed Nursing instructions

It designed after revising of literature of **(Gibbs and Ronald (2016))** It consisted of the following:

- **General information** about definition, benefits of botox....etc.
- **Nursing instructions before botox injection** that included the importance of investigations, persistence of allergy for specific medications, stopping of anticoagulant drugs for one week before botox injection, informed consent, fasting for 6 hours before injection, importance of reporting symptoms of urinary tract infections.
- **Kegel exercises:** It developed by researchers based on the content of the best practice statement for kegel exercises it involved the following: definition of kegel exercises, benefits of kegel exercises, cautions during exercises, step by step guide for performing kegel exercises. The patients should perform this exercise three times per day and started before operation and continued after discharge until symptoms relieved.
- **Nursing instructions during botox injection** that involved type of anesthesia, duration of the botox injection, patient position during injection
- **Nursing instructions after botox injection including;**
- **Voiding after the operation:** patient monitoring about degree of pain, burning, urgency, frequency and blood tinged urine following the procedure. These symptoms usually resolve within 2-5 days. Drink the amount of fluid it takes to keep the urine pink to yellow or clear in color. It may take a few

- days to a week to notice a gradual improvement in the overactive bladder symptoms.
- Also the nurse instructs the patient to minimize the risk factors that lead to recurrence of urinary incontinence post procedure include increased caffeine intake, and early management of constipation. Good controlled for diabetes mellitus by maintain normal level of glucose and urinary tract infections.
 - Also the nurse notifies the patient for minimize activity and do not lift more than fifteen pounds for 1-2 days. Also the nurse instructs the patient to eat good balanced diet high in vegetable and protein, low in fat to avoid constipation and maintain optimal level of health. Also wait at least 24 hours to drive.
 - **Pain control:** by taking narcotics for pain relief as **prescribed** consultation about blood thinners medication.
 - **Continuation of kegel exercises:** the nurse instructs the patient about;
 - The benefits of kegel exercises in strengthen the pubococcygeus muscle which supports the pelvic floor And improving urinary incontinence .
 - Inform the patient by steps of performance the exercises using simple Arabic language and illustrated teaching booklet was done and giving it for each patient with urinary incontinence and undergoing intravesical botox injection
 - **Follow up instructions:** the nurse should inform the patient about the warning signs after procedure as difficult to pass urine, excessive bladder pain, and fever. This can be a possible source of fever after the procedure. The nurse should advise the patients to continue kegel exercise until symptoms relieved.

Method

Administrative approval

Official approval and administration permission was obtained from the head of urology departments to collect the necessary data after explaining the aim and nature of the study.

Tools development

Tools were developed after extensive national and international literature review.

Validity:

The tools were tested for content validity by 5 experts from urology and nursing staff for content validity and reliability.

Ethical consideration

The study follows the common ethical guidelines of clinical research according to the principles of **Helsinki Declaration** for medical research, (1996).

- Research proposal was approved by ethical committee of the faculty of nursing.
- Informed consent was taken from patients participating study, after explaining the nature and purpose of the study.
- Confidentiality and anonymity were being assured.

Pilot study

A pilot study was conducted during November 2018. It included (10%) of the sample "3" patients for testing clarity and applicability of the study tools. Those patients who were involved in the pilot study were included in the main study as no modifications were done.

Operational design

Phase I: Preparatory phase

A review of current and past, local and international related literature in the various aspects of the problems using books, articles, periodicals, and magazines was done. The proposed study setting was assessed for the numbers of patients in the urology departments at Assiut Urology University Hospital. This phase ended by a pilot study.

Phase II: Implementation phase

- Data were collected at urology departments and urology outpatient clinic at Assiut Urology University Hospital in the period from January 2019 to December 2019
- The study tools and nursing instructions were formulated after review of literature.
- The researchers interviewed the patients individually and took their agreement to participate in the study after explaining their rights and the nature and purpose of the study.
- For the control group; after taking the patient oral agreement for voluntary participation in the study, the researcher then fills the patient's structured interview questionnaire sheet and numeric scale for pain (pre-operative and post nursing instructions).
- After the patient's discharge from the hospital, the researcher meets the patient for follow up in urology outpatient clinic after 6 months for re-evaluating the patient's condition and recurrence of urinary incontinence.
- For the study group; after filling the patient's structured interview questionnaire sheet and numeric scale for pain, the researcher explains to the patient nursing instructions preoperative, post-operative and before discharge.
- The study was carried out during morning and afternoon shift
- Study subjects were interviewed for 3 times; the first one for introducing the researchers, creating a line of communication, and pre-nursing instructions initial assessment and this meeting

lasts from 20-30 minutes. The second meeting involves the explanation of the information regarding the benefits of botox, meaning of botox injection, and preparation Prior to treatment, How are the injections administered , kegel exercises and finally patient's discharge advice following Intravesical botox and follow-ups appointments, this session lasts from 30-45 minutes hour. The last interview with the patient starts with a brief summary of the previous session, patient's feedback or questions about any ambiguous points, continuation of kegel exercises until symptoms relieved and it lasts for 20-30 minutes. Each patient was provided a written short, illustrated booklet on the nursing instructions previously mentioned and the researchers contact information (i.e. phone numbers) for any questions.

Phase III: Evaluation

Patients from study group were met 6 months from discharge for reevaluation and measuring the effect of the provided nursing instructions using **tool I (part three and part four), tool II.**

Statistical analysis

The data were verified for normality using the Anderson-Darling test and for homogeneity variances prior to further statistical analysis. Categorical variables were described by number and percent and continuous variables described by mean and standard deviation (Mean, SD). Chi-square test and fisher exact test used to compare between categorical variables where compare between continuous variables by t-test. A two-tailed $p < 0.05$ was considered statistically significant. All analyses were performed with the IBM SPSS 20.0 software.

Results

Table (1): Frequency distribution of patients in study and the control groups as regards demographic characteristics (n=30).

Demographic Data	Study (n=15)		Control (n=15)		P. value
	N.	%	N.	%	
Age					
20 < 30 years	10	66.7	12	80.0	0.291
30 < 40 years	5	33.3	2	13.3	
40 < 50 years	0	0.0	1	6.7	
Gender					
Male	7	46.7	7	46.7	1.000
Female	8	53.3	8	53.3	
Residence					
Urban	7	46.7	6	40.0	0.713
Rural	8	53.3	9	60.0	
Marital Status					
Single	9	60.0	11	73.3	0.439
Married	6	40.0	4	26.7	
Education Level					
Illiterate	0	0.0	1	6.7	0.232
Read and write	2	13.3	1	6.7	
Preparatory	2	13.3	1	6.7	
Secondary	2	13.3	7	46.7	
University	9	60.0	5	33.3	
Occupation					
Not working	9	60.0	12	80.0	0.232
Working	6	40.0	3	20.0	

*Chi-square test * Significant difference at p. value < 0.05*

Table (2): Comparison in frequency distribution between patients in study and the control groups as regards their medical data (n=30).

Medical data	Study (n=15)		Control (n=15)		P. value
	N.	%	N.	%	
Duration of disease					
Less than 1 year	0	0.0	4	26.7	0.026*
From 1-5 year	6	40.0	8	53.3	
More than 5 year	9	60.0	3	20.0	
Urgency					
No	10	66.7	14	93.3	0.068
Yes	5	33.3	1	6.7	
Dysuria					
No	15	100.0	14	93.3	0.309
Yes	0	0.0	1	6.7	
Urge sphincter spasm					
No	13	86.7	15	100.0	0.143
Yes	2	13.3	0	0.0	
Nervous bladder					
No	9	60.0	12	80.0	0.232
Yes	6	40.0	3	20.0	
Urinary incontinence					
No	6	40.0	3	20.0	0.232
Yes	9	60.0	12	80.0	

-Chi-square test * Significant difference at $p. value < 0.05$

Table (3):-Frequency distribution of the total score of patients' knowledge (study and control) pre and post nursing instructions.

	Pre				P. value	Post				P. value
	Study		Control			Study		Control		
	N.	%	N.	%		N.	%	N.	%	
Knowledge Level										
Unsatisfactory	14	93.3	15	100.0	0.309	1	6.7	10	66.7	0.001**
Satisfactory	1	6.7	0	0.0		14	93.3	5	33.3	

Chi-square test ** highly significant difference at $p. value < 0.01$

Table (4): Comparison between patients in the study and the control groups regarding Numeric Scale for assessment of pain pre and post nursing instructions

	Numeric Scale for assessment of pain				Z	P. value
	Study(n=15)		Control(n=15)			
	Mean \pm SD	Mean \pm SD	Mean \pm SD	Mean \pm SD		
Pre	3.73 \pm 1.49		4.27 \pm 1.67		-0.615	0.538
Post	1.2 \pm 0.68		3.4 \pm 1.76		-3.723	<0.001**

Mann-Whitney Test** highly significant difference at $p. value < 0.01$

Table (5): Frequency distribution of the studied patients as regarding recurrence of urinary incontinence post designed nursing instructions

Recurrence of urinary incontinence	Study		Control		P. value
	N.	%	N.	%	
Yes	3	20.0	9	60.0	0.030*
No	12	80.0	6	40.0	

Chi-square test * Significant difference at $p. value < 0.05$

Table (6): Correlation CO- efficient between recurrence of urinary incontinence, patients' knowledge and their pain for studied groups.

Items	Recurrence of urinary incontinence			
	Study		Control	
	R	P	R	P
Age	0.000	1.000	0.090	0.749
Gender	0.134	0.635	0.055	0.847
Residence	-0.200	0.474	-0.111	0.693
Marital Status	-0.068	0.810	-0.123	0.662
Education Level	0.066	0.817	0.169	0.546
Occupation	-0.068	0.810	0.068	0.810
Total Knowledge	-.536*	0.040*	0.099	0.726
Pain	0.01 **	0.01 **	0.086	0.762

** highly Statistically Significant difference at P. Value <0.01

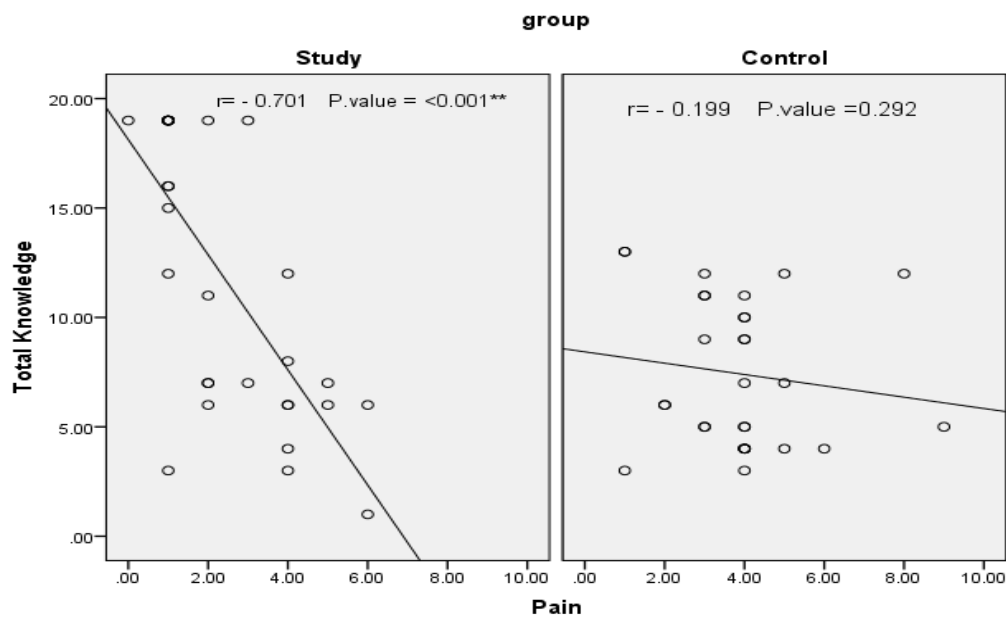


Fig (1): Correlation CO- efficient between patient knowledge and their pain for studied groups.

Table (1): Shows that the highest percentages of study and control their age were from 20 < 30 years (66.7 %, 80.0 %) respectively. Regarding to educational level it was found that the majority of study (60 %,.) was university education while in the control group (46.7%) was secondary education. Regarding to occupation it was found that (60%, 80%) were not working.

Table (2): Shows that the majority of patients in the study group had duration of disease more than 5 years was (60 %,.) while those in the control group had duration of disease from 1-5 years was (53.3%). Regarding urinary symptoms the highest percentages of both groups (study and control) had no symptoms such as urgency (66.7 %, 93,3%), dysuria (100% , 93,3%), urge sphincter spasm (86.7%,., 100 %) and nervous bladder (60%, 80%) and the highest

percentages of both groups (study and control) had urinary incontinence were (60%, 80%) respectively

Table (3): Shows that there was highly significant difference between the study and the control group after application of nursing instructions regarding the total knowledge of patients

Table (4): Shows that the mean score of numeric scale for assessment of pain among patients was 1.2 ± 0.68 in study group while in the control group it was 3.4 ± 1.76 post application of nursing instructions. There was significant difference between the study and the control groups post application of nursing instructions. $P < 0.01$

Table (5): Shows that in the study group one fifth of patients (20%) had recurrence of urinary incontinence while in the control group more than half (60%) post application of nursing instructions

and there was significant difference between the study and the control group post application of nursing instructions. $P=0.030$

Table (6): Shows that there was positive correlation between recurrence of urinary incontinence, patient knowledge and their pain for study group.

Fig (1): This figure illustrates that there was positive correlation between patient knowledge and pain for study group.

Discussion

Botulinum toxin (BTX) treatment for overactive bladder and detrusor over activity is becoming increasingly recognized as an excellent therapeutic option for treating patients (Arun et al., 2017)

Urinary incontinence is the uncontrolled leaking of urine while urge incontinence, urine leakage usually happens after a strong, sudden urge to urinate (American Urological Association, 2018).

Regarding demographic characteristics of patients, the present study showed that the highest percentages of patients in the study and the control groups their age were from 20< 30 years. These agree with the study of Stewart, (2014) who reported that the association of urinary incontinence with age is well characterized. Across all available studies, the age-specific incidence is <2 per 1,000 person-years in women <40 years of age.

Regarding gender the present study revealed that more than half of both group were female. This result agreed with Aoki et al., (2017) who stated that, urinary incontinence is the complaint of involuntary leakage of urine. Urinary incontinence symptoms are highly prevalent among women, have a considerable effect on health-related quality of life and are associated with considerable personal and societal expenses.

Also Bettez et al., (2012) supported this finding who reported that approximately 10% of people experience urinary incontinence at some point in adulthood, and incidence increases with age. Incontinence is approximately six times more common in females than in males.

The results in the present study revealed that; improvement in the knowledge score levels for patients in the study group after application of nursing instruction. These results agree with (Cynthia, 2017) who reported that health professionals provide patients with information to help them better understand their health needs and their diagnose disorders by providing access to this patient information.

In this regard; (Winslow, 2018) reported that patient with low level of reading or writing skills may lead to lack in following health care provider's instructions and causes lack knowledge of self-care. In the same

line these findings are supported by (Backman et al., 2018) who found that patient with low educational levels were less experienced than who with higher level of educational and this affect negatively on the knowledge and practices levels

In the same line Christina & Lee, (2018) stated that nurses are key to ensuring patients receive the care they need. A thorough knowledge of urinary incontinence and its treatment options allows nurses to answer patients' questions and make referrals as necessary. In addition, providing a comfortable atmosphere will help patients open up about their symptoms. Nurses Provide education about pelvic floor muscle training exercises, and symptom management and encourage them to learn more about their condition.

The present study showed that improvement in recurrence of urinary incontinence in study group and there was significant difference between patients in the study and the control groups post application of nursing instructions. This agree with (Filip et al., 2016) who revealed that botox is highly effective in reducing the troublesome symptoms caused by an overactive bladder - reducing the number of visits to the toilet, reducing the urgent desire to pass urine and to reduce recurrence of urinary incontinence. Symptoms improve quickly in the majority of patients.

Limitation of the study

- The research findings were limited and cannot be generalized because of the small sample size and it was selected from one geographical area in Egypt.
- Patients who does not comply with the scheduled follow up visits were excluded from the study
- Botox injections were not available in period of time so, taking more time to collect data

Conclusion

The findings of the study revealed that nursing instructions and kegel exercises were effective in improving outcomes (knowledge, minimize pain level and recurrence of urinary incontinence) for patients undergoing intravesical botox injection. There was positive correlation between recurrence of urinary incontinence, patient knowledge and their pain for study group.

Recommendations

In the light of the study findings, the following recommendations are suggested:

- Reapply this research on a larger probability sample acquired from different geographical areas in Egypt for generalization.

- Staff nurses should be trained to implement kegel exercises for patients to reduce recurrence of incontinence and pain level.
- Kegel exercises can be adapted as a standard of nursing care for patients with overactive bladder syndrome for patients undergoing intravesical botox injection.

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