

The Use of Botulinum Toxin as an Adjuvant in Managing Children with Chronic Constipation and Obstructed Defecation

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Abstract

Background: Pediatric chronic constipation and obstructed defecation is a challenging problem, with bad impact on quality of life affecting both the child and family. It is a complex disorder of multifactorial etiology and pathophysiology. Many symptoms-based systems have been instructed for clarifying definitions for chronic constipation and obstructed defecation such as ROME IV criteria, PACCT criteria, NICE guideline. Most protocols of management of functional constipation usually include; disimpaction enemas, feeding regulations, bowel diaries and laxatives.

Aim of Study: To evaluate the effectiveness of adding anal Botox injection to those already following management plan for pediatric age group suffering from chronic constipation and obstructed defecation.

Patients and Methods: The current study included 40 children with functional constipation, and obstructed defecation. The study started in April 2017 and completed the patients follow-up in November 2019. Bowel management program was applied with Botulinum toxin injection. Patients were followed-up at 2 months, and 6 months using Rintala Scores.

Results: The study included 45% female members and 55% male ones, with age range between 3-12 years. Improvement was achieved in 22.5% of children after 2 months of the management, all patients were followed-up at least for 6 months period, with a mean follow-up of 11.35 months. Rintala scores at initial presentation, 2 months and 6 months follow-up showed improvement. Overall, across all the study subjects, females did better and showed more improvement.

Conclusion: This study has confirmed that BT injection did not add any significant effect, to children with obstructed defecation and chronic FC.

Key Words: *Pediatric constipation – Chronic constipation – Functional constipation – Obstructed defecation – Anal sphincteric Botox injection.*

Introduction

FUNCTIONAL constipation (FC) is one of the commonest digestive complaints in children, which

has become quite a proportion in public health problem. Like many other functional disorders, its etiology, pathophysiology and prognosis are ill-understood. This made its management a current work in progress field to reach a better satisfying outcome for the children and their families [1,2].

As regards the clinical diagnosis of FC; the evaluation primarily consists of a thorough medical history and a complete physical examination. Additional investigations are not necessary in most cases. The physician should seek to understand the patient's perception of their current bowel habit, compared to the past and should include stool frequency, form and the ease of passage of stool. The use of the Bristol Stool Chart may aid the patient in their description of the stool form [3].

However, family physicians must be alert for red flags that may indicate the presence of an uncommon but serious organic cause of constipation, such as Hirschsprung's disease (congenital aganglionic megacolon), pseudo-obstruction, spinal cord abnormality, hypothyroidism, diabetes insipidus, cystic fibrosis, gluten enteropathy, or congenital anorectal malformation [4].

Treatment of functional constipation involves disimpaction using oral or rectal medication. Polyethylene glycol is effective and well tolerated, but a number of alternatives are available. After disimpaction, a maintenance program may be required for months to years because relapse of functional constipation is common. Maintenance medications include mineral oil, lactulose, milk of magnesia, polyethylene glycol powder, and sorbitol [1].

Despite treatment, only 50 to 70 percent of children with functional constipation demonstrate

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long-term improvement, hence the search for novel methods of treatment [4].

Aim of the work:

This study aimed to evaluate the effectiveness of adding anal Botox injection to those already following management plan for pediatric age group suffering from chronic constipation and obstructed defecation.

Patients and Methods

After obtaining the ethical committee approval, this study was conducted in Ain Shams University Hospital (El-Demerdash) at colorectal surgery and defecatory problems clinic. The study population was 40 pediatric patients referred to the clinic by symptoms suggestive of chronic constipation with or without over-flow retentive stool incompetence (ORSI), according to Rome III criteria. In addition, patients should also have symptoms suggestive of obstructive defecation.

Patients were excluded if they have spinal or neuromuscular abnormalities (e.g., spinal muscular atrophy, tethered cord), Currarino triad [rectal stenosis, hemi sacrum, presacral mass], cerebral palsy [static encephalopathy], hypothyroidism or a previous colorectal or anal surgery.

The 40 patients were managed with bowel management program and stimulant laxatives in addition to intra anal sphincteric Botox injection.

Botox injection as following:

After explaining the procedure to the caregivers and obtaining the informed consent. Patients received anal Botox injection under general anaesthesia. The patient received 33 IU of anal Botox injection at (3°, 6°, 9° o'clock lithotomy position), each region 11 IU. Injection was done from the perineal skin surrounding the anal verge, with index finger inside the anal canal. Using an Insulin syringe, directed upwards and inwards, until the tip of the needle is felt almost before the anal mucosa at dentate line (without piercing the mucosa). Post-injection the patients were given just oral analgesia up on request.

Follow-up plan:

Both groups were followed-up at 2 months, and 6 months using Rintala Scores. Any postoperative complications like infection or excoriation of urological symptoms were monitored.

Statistical analysis:

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM

SPSS) version 20 and the following were done: Qualitative data were presented as number and percentages while quantitative data were presented as mean, standard deviations and ranges. The comparison between two groups with qualitative data were done by using Chi-square test and/or Fisher exact test was used instead of Chi-square test when the expected count in any cell was found less than 5. The comparison between two paired groups with quantitative data and parametric distribution was done by using paired *t*-test. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the *p*-value was considered significant as the following: $p > 0.05$: Non-significant. $p < 0.05$: Significant. $p < 0.01$: Highly significant.

Results

Patients characteristics:

This study was conducted in the colorectal surgery and defecatory problems clinic of Pediatric Surgery Department of Ain Shams University hospitals, starting from April 2018 a total number of Forty pediatric patients with FC and obstructed defecation were included the study.

The majority of the patients were from the middle and lower social classes. Patients were referred from all over Egypt; yet, Cairo, Dakahlia and Monofia were the most common referring governorates.

It was noticed that, 80% of the study subjects have 2 brothers and or sisters or more, while 13% came from families of two children in total. Only 7% of children were the only child in their families (Fig. 1).

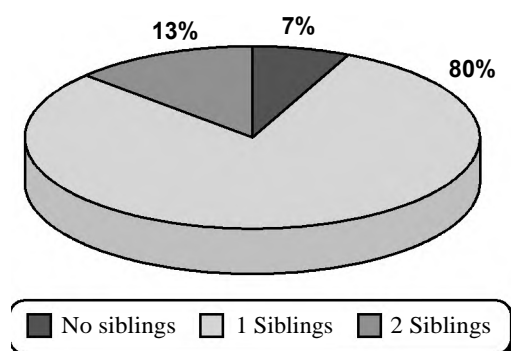


Fig. (1): Number of siblings among all study samples.

As regards the demographic data of the study population, it included 18 females representing; 45% and 22 males forming 55%, their average age was 6.9 years.

Follow-up and Rintala Scores results:

All patients were followed-up at least for 6 months period, with a mean follow-up of 11.35 months.

Rintala scores of both groups at initial presentation, 2 months and 6 months follow-up showed improvement over the 2 months and 6 months treatment period as shown. Overall, across all the study subjects, females did better and showed more improvement (Tables 1,2).

Management parameters:

Disimpaction retention enemas were applied to all patients prior the beginning of SBL. All the patients had twice per day enemas for a variable number of days, with a mean of 3.97 days (Table 3).

As regard SBL, most of the patients got their doses altered until reaching the adequate dose for maintenance. The mean maintenance dose was 31.75mg (Table 3).

Table (1): Comparison within male subjects.

	Before treatment	Score 2 months	Score 6 months	Before treatment - Score 2 months	Score 2 months - Score 6 months	Before treatment - Score 6 months
Mean	9.91	10.23	10.64	$t=-.389$	$t=-.734$	$t=-.594$
Std. Deviation	4.139	3.927	4.855	$p=.701$	$p=.471$	$p=.559$
Minimum	3	3	3			
Maximum	15	17	18			

Table (2): Comparison within female subjects.

	Before treatment	Score 2 months	Score 6 months	Before treatment - Score 2 months	Score 2 months - Score 6 months	Before treatment - Score 6 months
Mean	8.33	9.83	11.39	$t=-1.626$	$t=-1.279$	$p=-2.337$
Std. Deviation	4.379	3.899	4.889	$p=.122$	$p=.218$	$p=.032$
Minimum	3	3	3			
Maximum	15	16	18			

Table (3): Management parameters.

	Mean	Median	Std. Deviation	Minimum	Maximum
Number of days retention enemas needed to disimpaction	3.97	3	2.03	3	10
SBL in mg dose at no soiling	31.75	30	13.75	10	60
Follow-up period (months)	11.47	11	3.67	7	17

Noncompliance for the elements of bowel management program was noted in 3 patients with frequent reinstruction directed specifically for those children and their caregivers. None of the patients developed complication from the BT injection. Following the 6 months instillation of the management protocol, cessation of SBL was successful in 35 patients, with further longer-term course of SBL was prescribed for patients with unsuccessful management.

Discussion

Functional constipation in children is a worldwide problem, with increasing incidence during the last decades. This condition may progress overtime and represent a distressing-factor for both the child and his/her caregiver. This may affect the child well-being, and in instances the quality of life.

Many specialized clinics for managing FC in children are now available all over the world and in our country. These clinics should have a multi-disciplinary team approaching each individual case in the proper way, meeting the diagnostic criteria for each underlying cause of FC. The team should at least include pediatric gastroenterologist, pediatric surgeon, pediatric radiologist, and pathologist.

Ain-Shams Hospitals have a well-established colorectal surgery and defecatory problem clinic in its pediatrics hospital, since 2009. This clinic has a workload of 50-120 patients per clinic, almost 60-80% of the referred cases are suffering from FC. This clinic was established after a prototype structure designing, from similar clinic managed by Penna and his team in Cincinnati, USA.

The initial step in managing children with the intractable functional constipation is to do dis-

impaction, then run out a bowel management program, and to start stimulant laxatives. Senna based laxatives is the preferred laxative in this clinic, due to its availability and cheapness. Unlike PEG (the first choice used by many centres), which is usually unavailable in the Egyptian market, and if present, is so expensive. The aim of laxative therapy is to regain the adequate functional evacuation of the colon, with decreased possibility of stool re-loading.

The success rate of this management reached almost 85-90% in children with chronic FC. The non-responders are mainly the non-compliant patients, or those who are suffering for obstructive defecation (with severe straining and severe anal pain).

Targeting that group of non-responders by additional form of therapy is the role. Yet, the best treatment option is still yet undefined. Some centres may try behavioural therapy, biofeedback training, anal pain relief therapy, anal muscle complex relaxing therapy (i.e.; topical glycerine trinitrate), or intra anal sphincteric Botulinum toxin injection.

The expected role of intrasphincteric botulinum toxin injection was to relax the lower part of the anal sphincter, decreasing the forces required to propel the stools through the anal canal, and gradually reducing the dilated rectum, hence correcting the pathology and dynamics of obstructed defecation.

The objective Rintala score was used to detect the defecatory problems at diagnosis in all the included patients and after 2 and 6 months of management. Although, across all the study subjects, females did better and showed more improvement, yet no statistically significant difference in the Rintala defecatory scores all through the study period. This indicated that adding botulinum toxin injection to the management plan did not result in any functional improvement or added any benefits to the standard treatment protocol of FC.

Conclusion:

This study has confirmed that BT injection did not add any significant effect, to children with obstructed defecation and chronic FC.

References

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استخدام البوتوكس كوسيلة مساعدة فى علاج حالات الإمساك المزمن والإمساك الإنسدادي لدى الأطفال

بعد الإمساك المزمن تحدياً له تأثير سئ على نوعية حياة كلاً من الطفل والأسرة. وهو اضطراب متعدد الأسباب ويعتمد تشخيصه بصورة أساسية على التاريخ المرضي والفحص الطبي. ولقد تم وضع العديد من الأنظمة التشخيصية المعتمدة على الأعراض مثل معايير اجتماع باريس وروما ومعايير المعهد الوطنى للتميز فى الرعاية الصحية. وتتضمن معظم البروتوكولات العلاجية للإمساك الوظيفي المزمن عادة على الحقن الشرجية والأنظمة الغذائية ومدونات التبرز والملينات.

تضمنت الدراسة على ٤٠ طفلاً يعانون من الإمساك الوظيفي والإمساك الإنسدادي. تم تطبيق البروتوكول العلاجي بإضافة حقن البوتوكس وتمت المتابعة لجميع الحالات بعد شهرين وستة أشهر بمقياس رينتالا.

مثلت الإناث نسبة ٤٥٪ من أعضاء الدراسة ومثل الذكور ٥٥٪ تراوحت أعمارهم بين (٣:١٢) سنة تم تحقيق التحسن بنسبة ٢٢.٥٪ أطفال الدراسة بعد شهرين من تطبيق البروتوكول وتم متابعة جميع الحالات بعد ستة أشهر بمتوسط متابعة ١١.٣٥ شهراً. أظهرت نتائج رينتالا بعد شهرين وستة أشهر من المتابعة تحسناً. وعمامة كان للإناث أداء أفضل وحققوا تحسناً أكثر.

النتائج: أكدت هذه الدراسة أن حقن البوتوكس ليم يكن له إضافة مؤثرة للأطفال الذين يعانون من الإمساك الإنسدادي والإمساك المزمن.