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A Single Botulinum Toxin Injection in the Treatment of Strabismus: A Retrospective Analysis of 29 Patients

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Abstract

Objective: To describe the change in angle deviation, treatment effectiveness, overall safety, and cost effectiveness of the use of a single botulinum toxin injection session in the treatment of strabismus.

Methods: A retrospective analysis at a tertiary hospital in Amman, Jordan, to identify 29 patients who received a single botulinum toxin injection as a treatment of strabismus between October 2017 and March 2019. The outcome was determined by the improvement of the angle of deviation and avoidance of conventional muscle surgery. The safety profile was determined according to the incidence of adverse effects, such as overcorrection and ptosis. The economic profile included the medical and non-medical costs.

Results: The average of the total angles of deviation for the whole group improved in the first assessment visit in the first week post injection from 38.97 to 19.48 prism diopter (PD). However, the deviation started to increase after the first month and continued to increase, reaching 27.93 PD in the sixth month post injection follow up. About five of the 29 patients (17.2%) had a successful outcome (angle of deviation equal to or less than 10 PD) in the sixth month post injection, while around seven of the 29 patients (24.1%) had a partial improvement and 17 of the 29 patients (58.7%) had no improvement. Only two patients (6.8%) developed overcorrection. None of the patients developed ptosis or other adverse effects after injection. The total average cost of treatment, including medical and non-medical costs, was $410. The average medical cost was $305, while the non-medical cost was $105.

Conclusion: The use of a single botulinum toxin injection for treating strabismus is an effective, safe, and quick procedure to treat strabismus in some patients, especially those with mild and moderate angles of deviation. However, due to the temporary effect of the drug, it needs to be repeated for some patients and thus may be unsatisfactory in some circumstances.

Keywords: Botulinum Toxin, Strabismus, Botox, Esotropia, Exotropia

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Introduction

Strabismus is any misalignment of the eyes due to palsy or weakness of the cranial nerves (III, IV, VI) responsible for eye movement, problems in the eye movement control center in the brain or in eye muscles, or eye injuries. Accordingly, strabismus can be classified according to the direction of eye deviation: exotropia (outward deviation), esotropia (inward deviation), hypertropia (upward

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deviation), hypotropia (downward deviation), and cyclotropia (rotatory deviation). Moreover, strabismus could be classified based on the cause, time of onset, or whether it is constant or intermittent [1–4].

Strabismus occurs in up to 5% of the general population and up to 50% in populations with some underlying diseases such as cerebral palsy. There are many symptoms of strabismus, including, but not limited to, misalignment of the eyes, double vision, asymmetric eye movement, and frequent squinting or blinking. Currently, many treatment options for strabismus are utilized, primarily focused on visual axes alignment, with surgery being the main treatment modality. Surgery is used to change extraocular muscle function to alter ocular alignment, and botulinum toxin is applied to individual extraocular muscles to induce iatrogenic weakness and palsy in the injected muscle. This is supposed to result in good alignment of the eyes. Correction of refractive errors, treatment of amblyopia, prisms and orthoptic exercises are the main conservative options [1, 5–6].

Botulinum toxin is a neurotoxin protein produced by *Clostridium botulinum*, and related species, which blocks the release of the neurotransmitter acetylcholine at the neuromuscular junction from presynaptic axon endings, creating short chemical denervation. Due to its role in temporary muscular paralysis, sensory proprioceptive changes and the equilibrium of muscular forces in the injected muscle occur, promoting the alignment of ocular axes [6–9]. Botulinum toxin injection has been used for both diagnostic and therapeutic purposes. Diagnostic uses are mainly in the investigation of postoperative diplopia (double vision), while therapeutic uses concern the treatment of strabismus, facial muscle spasm, corneal ulceration, and nystagmus. The therapeutic uses for strabismus are to align the eyes for better cosmetic appearance, restore fusion, correct surgical under or overcorrections, and improve visual acuity in nystagmus by decreasing oscillopsia [6].

Botulinum toxin injection is recognized as both supplemental and alternative to surgery in treating strabismus [6–7, 9–10]. It can be given through single or multiple injections unilaterally or bilaterally, alone or combined with surgical and conservative treatments, and alone or with sodium hyaluronate [7, 11]. However, the efficacy of its use may differ according to the modality used and patient conditions [6–7].

A limited number of studies have described the clinical features, pattern of deviation change, effectiveness, overall safety, and economic profile of the use of a single botulinum toxin injection for treating strabismus [6–8]. Most studies investigating the use of botulinum toxin injections in the management of strabismus were mainly based on multiple injections and very few have studied the effect of a single injection session [7–8, 12–14. Few studies have discussed the mean change in the angle of deviation and the cost-effectiveness of this treatment [7, 12, 15]. As such, this study aimed to describe the clinical features, indications, pattern of angle deviation change, treatment effectiveness, overall safety, and cost effectiveness of the use of a single botulinum toxin injection for treating strabismus.

Materials and Methods

A retrospective study was conducted at a tertiary hospital in Amman, Jordan. After obtaining the approval of the Institutional Review Board, institutional medical records were used to retrospectively identify 29 patients with strabismus who had received treatment with a single botulinum toxin injection between October, 2018 and October, 2019.

The data included were patients' age, gender, type of strabismus, the muscle or muscles injected, angle of deviation preoperatively, and at one week, one month, four months, and six months postoperatively, as well as any postoperative adverse effects.

Injections were performed by one surgeon. The formulation of botulinum toxin A was Botox® (Allergan Ltd., High Wycombe, UK). One hundred IU were diluted with 2 ml of normal saline, subsequently obtaining an injection dosage of 5 units (0.1 ml) per muscle if a single muscle was injected and 2.5 units (0.05 ml) per muscle if two muscles were injected bilaterally. Several studies have used 2.5 IU to 7.5 IU per muscle, with the dose varying according to the degree of deviation [7]. Patients were injected under general anesthesia because of their young age (58.6% were children under 6 years old, with the mean age of the whole group being 7.22 years). For each patient, a speculum was placed as in standard ophthalmic surgery, and 5% povidone-iodine was placed in the conjunctival sac for 3 minutes before proceeding. The muscle (the medial or lateral rectus) was grasped with forceps; then, the needle was introduced under direct visualization subconjunctivally, a few millimeters from the muscle insertion, into the muscle belly, where botulinum toxin was injected.

The outcome was determined by the reduction in the angle of deviation postoperatively, and categorized as:

- Success: which indicates full control of the angle of deviation (10 or fewer prism diopters [PD]);
- Partial: which indicates partial control of the angle of deviation, or more than 10 PD and less than the original angle of deviation;
- Failure: which indicates no change, or overcorrection of more than 10 PD [6].

The safety profile was determined according to the incidence of adverse effects such as overcorrection and ptosis. The economic profile included the medical and non-medical costs including injection procedure, follow up visits, transportation, and costs of sick leave. IBM Statistical Package for the Social Sciences (SPSS) version 20 was used to analyze the data.

Results

Demographic Characteristics and Clinical Features

As Table 1 shows, the total number of patients in the study sample was 29. Most were females (n=16, 55.2%), had esotropia (n=18, 62.1%), and were aged less than six at the time of treatment (n=17, 58.6%); the mean age was 7.22 (SD=5.87). The mean angle of deviation before injection was 38.89 (SD=7.24) PD. Nineteen patients (65.5%) received the botulinum toxin injection bilaterally (bilateral medial rectus muscle injection in esotropia, and bilateral lateral rectus muscle injection in exotropia).

Table 1: Demographic Characteristics and Clinical Features

Demographic Characteristics and Clinical features	**Results**
Gender (n, %)	
• Male	13 (44.8%)
• Female	16 (55.2 %)
Age (Mean, SD)	7.22 (5.87)
Age (n, %)	

Demographic Characteristics and Clinical features	Results
• Less than 6 years	17 (58.6 %)
• 6–17 years	9 (31.1 %)
• Over 18 years	3 (10.3 %)
Type of strabismus	
• Esotropia	18 (62.1%)
• Exotropia	11 (37.9 %)
Pre-treatment deviation PD (Mean, SD)	38.89 (7.24)
Number of Injected Muscles	
• One muscle	10 (34.5%)
• Two muscles	19(65.5 %)
Total	29 (100%)

* *Prism diopters (PD)*

Angle of Deviation after Injection

As Figure 1 shows, the mean angle of deviation of the whole group of patients decreased significantly during the first assessment visit (the first week post injection) from 38.97 to 19.48 PD. However, the deviation increased after the first month and continued to increase, reaching 27.93 PD in the sixth month post injection. The number of patients who had up to 10 PD was 10/29 patients in the first week post injection, 9/29 patients in the first month post injection, 6/29 patients in the fourth month post injection, and 5/29 patients in sixth month post injection.

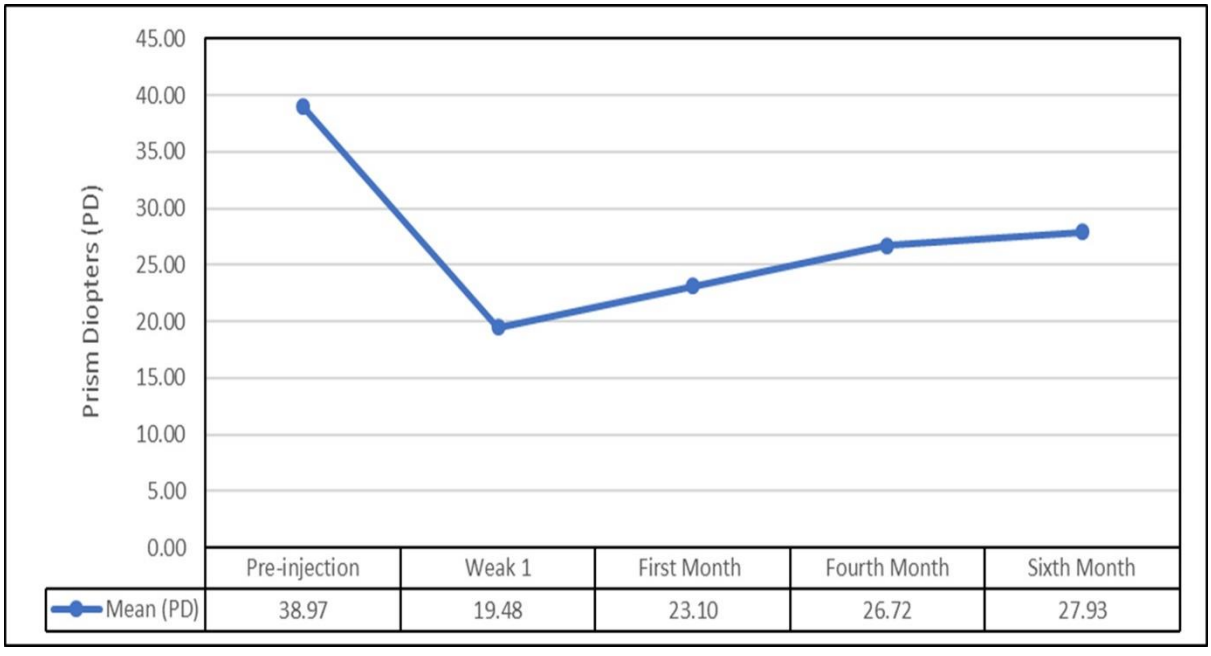

Figure 1: Angle of Deviation Mean Value after Injection

Table 2 shows that there was a statistically significant reduction (28.32%, p=0.004) in the mean angle of deviation for the whole group before injection and at the sixth month post injection.

Table 2: Angle of Deviation after Injection for Total Cohort and by Demographic Characteristics and Clinical Features

Demographic Characteristics and Clinical features	Pre-Treatment Angle of Deviation in PD (Mean, SD)	Angle of Deviation after Injection (Mean, SD)				Reduction in Deviation: Mean, (Percentage) *	*p* value
		One Week	One Month	Four Months	Six Months		
Gender • Male • Female	40.4 (9.0) 37.8 (5.5)	24.2 (17.1) 15.6 (15.5)	28.1 (18.8) 19.1 (15.7)	33.8 (15.8) 20.9 (15.5)	33.5 (15.9) 23.4 (14.6)	6.6 (16.53%) 14.4 (38.78%)	.063**
Age (Years) • Less than 6 • 6–17 • 18 and more	36.9 (7.0) 42.5 (7.5) 38.3 (2.9)	13.1 (16.2) 26.0 (15.4) 31.7 (2.9)	17.8 (17.5) 29.0 (17.3) 31.7 (10.4)	20.6 (17.0) 35.0 (13.7) 31.7 (14.4)	22.8 (16.4) 35.0 (12.9) 31.7 (14.4)	14.1 (37.53%) 7.5 (17.78%) 6.7 (19.05%)	.463**
Type of strabismus • Esotropia • Exotropia	37.8 (8.1) 40.9 (5.4)	15.6 (16.8) 25.9 (14.5)	19.7 (17.4) 28.6 (16.9)	24.4 (15.6) 30.5 (18.5)	26.7 (14.3) 30.0 (18.3)	11.1 (28.9%) 10.9 (28.64%)	.661**
Number of Injected Muscles • One Muscle • Two Muscles	42.0 (5.4) 37.4 (7.7)	20.5 (13.0) 18.9 (18.4)	24.5 (17.9) 22.4 (17.7)	25.5 (17.9) 27.4 (16.5)	28.5 (15.5) 27.6 (16.3)	13.5 (33.43%) 9.7 (26.37%)	.336**
Total	38.97 (7.24)	19.48 (16.49)	23.10 (17.44)	26.72 (16.71)	27.93 (15.73)	11.03 (28.32%)	**.004*** **

*Mean difference between pre-treatment deviation and deviation at the 6th month after injection

**Mann Whitney U (between two groups) and Kurskal Walis (between three groups) tests was used to measure the differences in reduction in the mean of the angle deviation reduction mean

***One-Sample Kolmogorov-Smirnov Test was performed between the means of angle of deviation in pre-treatment and 6th month after injection

BOLD means that the difference is significant at alpha=0.05 level.

The highest percentage of improvement in the angle of deviation six months post injection was found among female patients (reduction mean=14.4 PD, 38.78%), patients under six years (reduction mean=14.1 PD, 37.53%), patients with esotropia (reduction mean=11.1 PD, 28.9%), and patients who underwent injection in one muscle (reduction mean=13.5 PD, 33.43%). The lowest percentage of improvement in the angle of deviation six months post injection was found among male patients (reduction mean=6.6 PD, 16.53%), patients aged over 18 (reduction mean=6.7 PD, 19.05%), patients with exotropia (reduction mean=10.9 PD, 28.64%), and patients who underwent bilateral injection (reduction mean=9.7 PD, 26.37%). These results, although clinically important, showed statistically insignificant differences in mean reduction in the angle of deviation values according to patient gender, age group, type of strabismus, and number of injected muscles

(p>0.05). This is mainly due to the small sample size, which does not imbue statistical power.

Treatment Effectiveness

As Figure 2 shows, 5/29 patients (17.2%) had a successful treatment (angle of deviation was equal to or less than 10 PD) in the sixth month post injection, while around 7/29 patients (24.1%) had a partial improvement and 17/29 patients (58.7%) had no improvement.

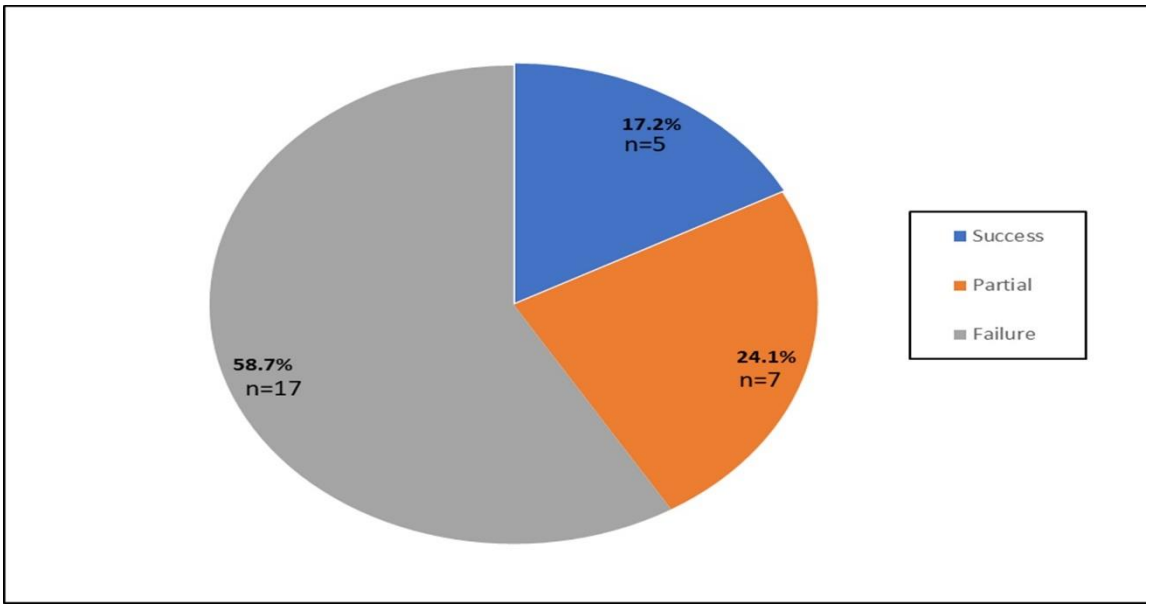

Figure 2: Outcome after Six Months Post- Treatment

Treatment effectiveness according to demographic and clinical features is shown in Table 3. Five patients had successful results: all were aged less than 6 years (100%), three were female and diagnosed with esotropia (60%), and four received the injection bilaterally (80%).

Table 3: Treatment Effectiveness for Total Cohort and by Demographic Characteristics and Clinical Features

Demographic Characteristics and Clinical Features	Outcome after Six Months Post- Treatment n (%)		
	Success (n=3)	Partial (n=6)	Failure (n=20)
Gender			
• Male	2 (40.0%	1 (14.3%)	10 (58.8%)
• Female	3 (60.0%)	6 (85.7%)	7 (41.2%)
Age			
• Less than 6 years	5 (100.0%)	2 (28.6%)	9 (52.9%)
• 6–17 years	0 (0%)	4 (57.1%)	6 (35.3%)
• Over 18 years	0 (0%)	1 (14.3%)	2 (11.8%)
Type of strabismus			

• Esotropia	3 (60.0%)	4 (57.1%)	11 (64.7%)
• Exotropia	2 (40.0%)	3 (42.9%)	6 (35.3%)
Number of Injected Muscles			
• One muscle	1 (20.0%)	5 (71.4%)	4 (23.5%)
• Two muscles	4 (80.0%)	2 (28.6%)	13 (76.5%)
Total	5 (17.2%)	7 (24.1%)	17 (58.7%)

Most patients who had partial improvement were female (85.7%), aged between 6–17 years old (57.1%), diagnosed with esotropia (57.1%), and received the injection bilaterally (71.4%). Likewise, most patients who had no improvement were male (58.8%), aged less than 6 years (52.9%), diagnosed with esotropia (64.7%), and received injection bilaterally (76.5%).

Adverse Effects

Our study showed an excellent safety profile. Only two patients (6.8%) developed overcorrection: one was a transient exotropia which had completely resolved by the end of the follow up period and the other developed a large overcorrection that had partially resolved by the end of the follow up period but necessitated surgical correction. None of the patients developed ptosis after injection.

Economic Profile

Our analysis showed that the total average cost of treatment, including medical and non-medical costs, was $410. The average medical cost was $305, while the non-medical was $105. The costs of the medical injection procedure and patient follow up were $250 and $55, respectively. Moreover, there were other non-medical costs, such as transportation and sick leave. The average cost of transportation and leave costs were $45 and $60, respectively. See Table 4.

Table 4: Economic Profile

Cost	Average Cost ($)
Medical Cost	
• Injection Procedure	$250
• Follow Up	$55
• Total	$305
Non-Medical Cost	
• Transportation	$45
• Leave including companion	$60
• Total	
• **Overall Total**	$ 105
	$ 410

Discussion

Our study investigated the use of a single botulinum toxin injection for the treatment of strabismus. The results showed how the botulinum toxin changed the mean angle of deviation. The effect of the injection started soon afterwards and improved the angle of deviation for 10/29 patients in the first week.

However, this effect started to decrease significantly after the first month.

Our results showed that there was a statistically significant difference in average angle of deviation values before injection and in the sixth month post injection (mean reduction=11.03 PD, 28.32%, p=.004). However, this difference was not clinically significant for some patients (24/29 patients) who had their strabismus improved but still higher than 10 PD after the sixth month post injection. These patients will either need repeated injections or surgical treatment to achieve a satisfactory outcome for their strabismus.

Moreover, our results showed lower success rates compared to other studies, such as a systematic review and meta-analysis study that included nine studies which showed that the mean reduction of angle of deviation was 30.7 PD (95% CI) [7]. The difference in success rates may be due to the fact that most of the studies (6/9 studies) included in the analysis discussed repeated botulinum toxin injections. Moreover, the review article mentioned only one type of strabismus (infantile esotropia) while we discussed patients with both esotropia and exotropia. Another study conducted by Scott et al. [18] showed that the percentage of mean reduction in the angle of deviation was 61% among patients who were treated with single injection [15].

The results in our study showed statistically insignificant differences in the mean values of reduction of deviation only according to patient demographic and clinical features (p>0.05), despite their clinical importance. However, some of these differences and observations may be related to our small sample size, which does not confer statistical power. These results were consistent with many findings from other researchers [9, 12].

The highest reduction in deviation at the sixth month post injection was found among patients aged under six years. This indicated the role of early treatment in improving the outcome. Additionally, the highest reduction was found among patients with esotropia, which is consistent with a previous study that indicated the same level of reduction in angle of deviation [8].

According to the results of previous studies, the success rate of using botulinum toxin injection varied widely from 33% [16] to 100% [17]. A systematic review with meta-analysis was performed in 2017 to measure the efficacy of botulinum toxin in the treatment of strabismus and evaluate its complication rates. Nine studies were included in this analysis. The results showed that success rate was 76% [7]. The success rate of a single botulinum toxin injection was 24.5% [13] to 88% [14]. Scott et al. [18] showed that 61% of all esotropia, 66% of infantile esotropia, and 45% of all exotropia cases had a successful result at six months after injection, considering that the average number of injections per patient was 1.7 injections. About 59% of patients had successful results after being treated with a single injection, and about 62% of patients had a successful result after two injections [15]. De Alba Campomanes showed that the success rate of first, second, and third injections were 24.5%, 41.3%, and 45%, respectively [13]. Another study showed the percentage mean reduction in angle of deviation was 61% among patients treated with a single injection, while the percentage among patients treated with repeated injections was 67% [15].

The divergence from our results may be related to the fact that most of the patients in our study had a high angle of deviation (mean=

38.97 PD), which makes achieving successful results more difficult. Moreover, our study included patients of different ages ranged from 9 months to 24 years, and different types of strabismus, which made a comparative analysis of each impossible. Therefore, the small sample size could have affected the results and final success rate. Finally, late presentation to the clinic delays strabismus treatment and negatively affects the outcome of this treatment.

Our results showed that only two patients (6.8%) developed overcorrection, which is better than the results in [7–8]. Solebo [8] indicated that 41% of the sample developed adverse outcomes after injection. Around 26% of patients developed overcorrection and 39% developed ptosis [8]. Issaho [7] indicated that the complication rate was 1% (95% CI: 0–2%) for consecutive exotropia (XT), 27% (95% CI: 21–33%) for ptosis, and 12% (95% CI: 4–22%) for vertical deviation [7]. Rowe and Noonan [6] indicated that the complications of botulinum toxin injection included vertical deviation (range 8.3–18.51%) and ptosis (range 9–41.66%).

The study has several limitations. The main limitation for this study was its retrospective nature, which made standardizations of treatment difficult. Also, mixed types of strabismus were included and comparative analysis of each was impossible due to the small sample size, which could have affected the results. Further studies are needed to discuss the efficacy of a single botulinum toxin injection for treating strabismus using a large sample size, a prospective comparative approach to measure efficacy, and a longer follow up duration.

Conclusion

Botulinum toxin injection of extraocular muscles is a recognized and established modality of treating strabismus. Our study concluded that the use of a single botulinum toxin injection for strabismus achieved satisfactory results and was cost effective compared to other treatment modalities with a low complication rate. Also, patients had a faster postoperative recovery and quicker return to daily life (school or work). It was most effective in the younger age group with a mild to moderate angle of deviation. It may be used as a quick surgical procedure (under mask anesthesia) especially in hospitals where there is a long waiting list for surgery, the cost of surgery is very high, or the lack of an experienced strabismus surgeon. Repeated injections may be considered in a selected group of patients to achieve a better outcome.

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حقن توكسين البوتولينوم المنفرد في علاج الحول: تحليل بأثر رجعي لـ 29 مريضًا

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الملخص

الهدف: وصف التغيير في زاوية الإنحراف، وفعالية العلاج، والسلامة العامة، وفعالية التكلفة لاستخدام جلسة حقن توكسين البوتولينوم المفردة لعلاج الحول.

الطريقة: تحليل بأثر رجعي في مستشفى متقدم في عمان، الأردن، لتحديد 29 مريضًا تلقوا حقنة واحدة من توكسين البوتولينوم كعلاج للحول بين تشرين الأول 2017 وآذار 2019. تم تحديد النتيجة من خلال تحسن زاوية الانحراف وتجنب جراحة العضلات التقليدية. تم تحديد ملف الأمان وفقًا لحدوث الآثار الضارة مثل التصحيح المفرط وتدلي الجفون. تضمن الملف الاقتصادي التكاليف الطبية وغير الطبية.

النتائج: تحسن متوسط الزوايا الكلية للانحراف للمجموعة بأكملها في زيارة التقييم الأولى في الأسبوع الأول بعد الحقن من 38.97 إلى 19.48 درجة منشورية .(PD) ومع ذلك، بدأ الانحراف في الزيادة بعد الشهر الأول واستمر في الزيادة، حيث وصل إلى 27.93 PD في الشهر السادس بعد متابعة الحقن. كان لدى حوالي 29/5 مريضًا (17.2٪) نتيجة ناجحة) زاوية الانحراف تساوي أو أقل من 10 (PD في الشهر السادس بعد الحقن بينما كان لدى حوالي 29/7 مريض (24.1٪) تحسن جزئي و29/17 مريضًا (58.7) ٪ (لم تتحسن. أصيب مريضان فقط (6.8٪) بتصحيح مفرط. لم يصاب أي من المرضى بتدلي الجفون أو آثار ضارة أخرى بعد الحقن. بلغ إجمالي متوسط تكلفة العلاج، بما في ذلك التكاليف الطبية وغير الطبية، 410 دولارات. وبلغ متوسط التكلفة الطبية 305 دولارات، بينما كانت التكلفة غير الطبية 105 دولارات.

الخلاصة: إن استخدام حقنة واحدة من توكسين البوتولينوم لعلاج الحول كان إجراءً فعالاً وآمنًا وسريعًا لعلاج الحول لدى بعض المرضى، خاصة في زوايا الانحراف الخفيفة والمتوسطة. ومع ذلك، بسبب التأثير المؤقت الدواء فإنه يحتاج إلى تكراره لبعض المرضى والتي قد تكون غير مرضية في بعض الظروف.

الكلمات الدالة: توكسين البوتولينوم، الحول، البوتوكس، الحول الأنسي، الحول الوحشي.