

Comparing Botulinum Toxin Versus Lord's Procedure in Patients with Chronic Anal Fissure: A Prospective Study

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Abstract

Introduction: Anal fissure (AF) is a common disease. It causes considerable discomfort, loss of working days, and reduction in quality of life. Symptoms of AF include anal pain during defecation and bleeding per anus. Acute AF is treated conservatively, but chronic AF (CAF) does not usually respond to conservative treatment. Anal stretch (Lord's procedure), reintroduced into AF therapy in 1964 with significant success rates, is, however, associated with recurrence rates varying from 2% to 80%, a high risk of incontinence (up to 51%), and is widely criticized despite a reported cure rate of approximately 90%.

Materials and Methods: The present prospective study was conducted after due approval of "Scientific and Ethical Committee" in the Department of General Surgery of Mata Chanan Devi Hospital, New Delhi, during the period from October 2013 to May 2015 on patients attending the outpatient department or emergency department of this hospital.

Results: In the present study, all 50 patients were selected and randomized into two treatment groups. Results were compared among two groups: Group B: Patients receiving Botulinum toxin-A (BOTOX) injection ($n_1 = 25$) and Study Groups Group1=Group-B, Group-2=Group-D. Randomisation Will Be As Follows. Group-B (Botox) Vs Group-D(Lords Procedure): Patients who underwent Lord's procedure ($n_2 = 25$). All results are well tabulated and described in figure format for well understanding in main article.

Conclusion: BOTOX is as good as an option, compared to ancient yet routinely practiced LORD'S anal dilatation technique for CAF. BOTOX significantly reduces pain in patients with CAF as compared to Lord's procedure. BOTOX has definite action in reducing the spasm of internal anal sphincter which is the chief cause of development of CAF. Spasm significantly improves with BOTOX compared to Lord's procedure.

Key words: Botulinum toxin-A, Fissure, Pain

INTRODUCTION

Anal fissure (AF) is a common disease. It causes considerable discomfort, loss of working days, and reduction in quality of life.^[1]

It was first described by Recamier in 1829 who recommended stretching the anal sphincter to treat this condition.^[2] AF affects all age groups, particularly young adults. 90% of all fissures occur posteriorly and 10%

anteriorly. Less than 1% of patients have both anterior and posterior fissures.^[3]

Symptoms of AF include anal pain during defecation and bleeding per anus.^[4] Acute AF is treated conservatively with a fiber supplement, stool softeners, and generous intake of water along with sitz baths and local anesthetic ointment, which usually bring about complete healing.^[5] However, chronic AF (CAF) does not usually respond to conservative treatment.

The internal sphincter spasm is the main factor in the pathogenesis of CAF.^[6] Therefore, the treatment of this condition is aimed to reduce the internal sphincter hypertonia.^[7] The basal tone of the internal anal sphincter (IAS) is affected by various substances, including nitric oxide (NO).^[8] In patients with AFs, the synthesis of NO in the IAS is reduced in comparison with the controls.^[9]

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Manometry studies have demonstrated an increased IAS tone and a reduction in anodermal vascular blood flow, mainly in the posterior region,^[10,11] and showed that, in patients who benefited from sphincterotomy surgery or from anal stretch (Lord's), sphincter hypertonia was reduced and blood flow increased. This pathogenetic mechanism can explain the achievement of a high rate of healing with medical therapies able to improve blood flow^[12] and/or to reduce hypertonia.^[13]

Anal stretch (Lord's procedure), reintroduced into AF therapy in 1964^[14] with significant success rates,^[15] is, however, associated with recurrence rates varying from 2% to 80%,^[16,17] a high risk of incontinence (up to 51%),^[18,19] and is widely criticized despite a reported cure rate of approximately 90%.^[16]

More recently, an attempt was made to standardize anal dilatation with pressurized balloons (controlled pneumatic dilatation) to reduce the incidence of sphincter injury with appreciable results.^[20,21] Recent studies, however, claim that anal stretch operation could be effective if done by experienced hands and there is a need to reconsider its merits over lateral internal sphincterotomy (LIS).

LIS is the most frequently performed surgical procedure for the treatment of CAF which results in healing rate of 90–95%.^[3] It works by reducing the sphincter hypertonia which is the main etiological factor in the development of CAF.^[6] It may cause minor but permanent incontinence.^[22] Several therapeutic alternatives were proposed to reduce anal pressure leaving the sphincter ring intact to avoid incontinence.^[5,6]

Botulinum toxin (BOTOX) injection in the internal sphincter muscle has become an acceptable alternative for internal anal sphincterotomy.^[22-24] It eliminates the spasm of the IAS by blockage of neurotransmission without IAS muscle disruption (chemical sphincterotomy).^[24,25] We aimed, in this study, a comparison of BOTOX versus Lord's procedure for healing in chronic fissure in ano patients.

MATERIALS AND METHODS

The present prospective study was conducted after due approval of "Scientific and Ethical Committee" in the Department of General Surgery of Mata Chanan Devi Hospital, New Delhi-59, during the period from October 2013 to May 2015 on patients attending the outpatient department (O.P.D) or emergency department of this hospital.

Study Design and Duration of the Study

This is a prospective study of the patients who are presented to General Surgery O.P.D/emergency department of Mata Chanan Devi Hospital and who are diagnosed with CAF.

This study was conducted during October 2013–May 2015 and patients were chosen irrespective of their unit of visit to surgery OPD.

In all, 50 patients were selected in this study. Using computer-generated random sequencing numbers, two groups were made with alphabet B (BOTOX injection) and L (Lord's procedure) and incoming patients were assigned to the respective groups on the basis of this random sequencing. The advantages and disadvantages of both these procedures were explained to the patients in the language in which they best understand. Only those patients who gave valid written consents were only included in this study.

Inclusion Criteria

The following criteria were included in the study:

1. Patients who are symptomatic for AF but not responding to medical treatment for >6 weeks.
2. Patients diagnosed as CAF (>6 weeks) who had not received any surgery in the past.
3. Patients who agreed to give a valid written consent for this study.

Exclusion Criteria

The following criteria were excluded from the study:

- Subjects who were unwilling to have an examination of AF/who failed to give written consent.
- Subjects who have had lateral sphincterotomy or anal stretch or other previous surgery involving the anal canal or perianal region.
- Subjects with complicated fissure with cicatricial deformation.
- Patients with hemorrhoids.
- Patients with accompanying large sentinel pile mass/masses.
- Subjects with AF associated with other conditions (drug-induced [e.g. nicorandil], trauma, fistula-in-ano, inflammatory bowel disease, perianal sepsis, or malignancy).
- Anal abscess.
- A history of radiation therapy to the pelvis.
- Fixed anal stenosis/anal stricture.
- Subjects with a history of neoplastic disease within 5 years (except for basal cell carcinoma or non-metastatic squamous cell carcinoma of the skin).
- Subjects with a clinically significant history of renal, hepatic, neurological, dermatological, immunological, major psychiatric (including drug or alcohol abusers), or hematological illness.
- Subjects who will be unavailable for the duration of the trial, likely to be noncompliant with the protocol, or who are felt to be unsuitable by the investigator for any other reason;
- Women who are pregnant or breastfeeding.

Procedure of the Proposed Study

Lord's procedure

This old technique was first developed for the treatment of hemorrhoids. It involves progressive-controlled manual dilatation of IAS by the surgeon. Patient is kept in lithotomy position/left lateral position under general/caudal anesthesia, surgeon introduces his fingers into the anal canal, and manual stretching of the non-striated IAS fibers is then done. One finger, two fingers, and successively four fingers are introduced, and manual stretching of fibers is done. Hegar's dilator 20–26 mm can also be used.

BOTOX injection

The patients were injected with Onabotulinum toxin Type-A (BOTOX, Allergan). A total dose of 20-U to 25-U was diluted in 4 ml isotonic saline and injected while the patient lies on his/her left side. An insulin syringe and a 26-G needle were used for injection. The injection was given into the IAS. Half of this dose was injected on both the sides of the fissure at 3 and 9 o'clock positions and at the base in few cases. Local anesthesia may/may not be given depending on the case. The patients would be followed up on day 1, 1st week, 2nd week, and at the end of 4 weeks until the fissure was healed. The patients' records were reviewed for improvement in pain, using visual analog assessment for pain, bleeding, constipation assessed by standard protocol, use of additional laxatives, incontinence scores, windy colic's in abdomen, quality of life improvement as well as recurrence of symptoms.

Data Collection Tools and Techniques

Pain was assessed by visual analog scale (V.A.S). Healing was defined as complete re-epithelialization of fissure and absence of pain. The continence severity was assessed according to the validated Cleveland Clinic Incontinence Scoring (C.C.I.S) System because it is practical and easy to use and interpret. It involves giving points for each mode of anal incontinence, whether gas (1–3), liquid stool (4–6), solid stool (7–9), or the requirement of wearing a pad (1–3) according to frequency (occasionally, >1/week or daily), respectively. The Cleveland Clinic Score (C.C.I.S) is a sum total of these points:

0=Perfect continence

1–7=Good continence

8–14=Moderate incontinence

15–20=Severe incontinence

21=Completely incontinent.

The treatment was considered successful if complete healing of fissure occurred within 4 weeks after treatment. Unhealed fissures were considered as treatment failures. Recurrent fissures were defined by the relapse of fissure symptoms and loss of epithelialization, with exposure of horizontal fibers of the IAS at its floor at a later follow-up

examination, following a complete healing. All data were documented and analyzed.

All procedures in Group-B Vs Group-D were done by experienced surgeon irrespective of his unit, with majority procedures done by the concerned unit. The study incorporated all such procedures, including the procedures done by investigator himself under the guidance of senior consultant surgeon. The patients were discharged when there was no pain, bleeding and when vitals were stable.

Tools

Tools were used in the form of questionnaire and checklist, P.I.S, V.A.S for pain, Cleveland Clinic Scoring System (C.C.I.S) for grading of incontinence, patient assessment of constipation (P.A.C), and quality of life questionnaire.

1. V.A.S: The concept of visual analog score was explained to each patient before the start of treatment with maximum imaginable pain as 10 and least as 1. The patient was assessed for pain by VAS at day 1, 1st week, 2nd week, 4th week, and the end of 6th week and 6 months.

Statistical Analysis

For statistical analysis, Statistical Package for the Social sciences version 15.0 is used for statistical analysis. Statistical significance was defined as $P < 0.05$. The quantitative variables are expressed as mean \pm standard deviation and compared between groups using unpaired *t*-test and within groups across follow-ups using paired *t*-test. All the comparisons are summarized in respective tables and respective graphs are made to assist understanding and enhance visual appeal. The qualitative variables are expressed as frequencies/percentages and compared using Chi-square test. $P < 0.05$ is considered to be statistically significant.

RESULTS

This is a prospective study comparing Lord's versus BOTOX in patients with CAF. This study was done during October 2013 to May 2015 in the Department of General Surgery, Mata Chanan Devi Hospital, New Delhi.

In this study, in all, 50 patients were selected and randomized into two treatment groups. Results were compared among two groups.

- Group B: Patients receiving BOTOX injection ($n_1 = 25$)
 - Group 2: Patients who underwent Lord's procedure ($n_2 = 25$).
1. Age distribution: In this study, of 50 patients, the lowest age group in Group B was 28 years, while in Group L was 26 years. The eldest patient's age

in both the groups was incidentally the same (65 years). Mean age of the patients in Group B was 38.64 ± 9.05 years and the same in Group L was 39.24 ± 9.04 years. With $P = 0.410$, there was no significant difference in age distribution between the two groups [Table 1].

2. Gender distribution: Table 2 shows a comparison of gender between the two groups. It was observed that, in Group B, 56% of the study subjects were males and 44% were females. Under Group L, 60% of the patients were males while 40% were females, with $P = 0.387$. Thus, there was no statistical difference between gender distributions between the two groups. Male:female ratio was 1.32:1 [Table 2].
3. Comparison of proctoscopy findings: The most common site of fissure-in-ano was posterior (PF) constituting 82% of the cases. 10% fissures were anterior (A.F). Five patients had anterior fissures, of which only one was a male. 8% of patients had both posterior and anterior fissures.

Sentinel tag was observed among 16% of the patients of 50. In this study, there was no significant difference between the two groups as regards the location of fissure with $P > 0.05$ [Table 3].

4. Sphincter spasm: Table 4 shows a comparison of sphincter spasm between the two groups. I.A.S spasm was present among 76% patients of 50.

We found no significant difference between the two groups as regards sphincter spasm with P -value $0.254 > 0.05$ [Table 4].

Table 1: Age distribution

| Age (years) | BOTOX | Lord's |
|-------------|------------|------------|
| | n (%) | n (%) |
| <30 | 3 (12) | 2 (8) |
| 30-40 | 14 (56) | 13 (52) |
| 40-50 | 5 (20) | 7 (28) |
| 50-60 | 2 (8) | 2 (8) |
| 60-70 | 1 (4) | 1 (4) |
| Total | 25 (100) | 25 (100) |
| Mean±SD | 38.64±9.05 | 39.24±9.40 |
| P-value | 0.410 | |

SD: Standard deviation, BOTOX: Botulinum toxin-A

Table 2: Gender distribution

| Gender | BOTOX | Lord's | P-value |
|--------|----------|----------|---------|
| | n (%) | n (%) | |
| Male | 14 (56) | 15 (60) | 0.387 |
| Female | 11 (44) | 10 (40) | |
| Total | 25 (100) | 25 (100) | |

BOTOX: Botulinum toxin-A

5. Comparison of pain score:

Table 5 shows a comparison of pain score on V.A.S preoperatively and during each follow-up visits at the end of 2 weeks and 4 weeks.

1. Preoperative V.A.S score: Mean V.A.S score preoperatively was 7.4 ± 1.66 in Group B, and in Group L, it was 7.92 ± 1.29 (S.D). P -value of the study of pre-operative VAS score was found to be 0.111 which is >0.05 . Thus, there was no statistically significant difference between pain scores between the two groups before the start of the study and that the pain scores were comparable.
2. V.A.S at 2 weeks: At the end of 2 weeks, V.A.S score was 1.32 in Group B and it was 4.36 in Group L, with a $P < 0.001$. Thus, there was a statistically significant difference between V.A.S scores, and pain was more with Lord's as compared to BOTOX.

V.A.S at 4 weeks.: At the end of 4 weeks, mean V.A.S score in Group B was 0, while it was 0.24 in category Lord's with $P = 0.013$. Thus, there was a statistically significant difference in V.A.S scores at the end of 4 weeks between the two groups with BOTOX showing improvement in pain compared to 3. Lord's procedure [Table 5].

6. Comparison of fissure healing:

Table 6 shows the comparison of mean duration of fissure to heal with either BOTOX or Lord's procedure.

In this study, fissure healed in 92% of patients receiving BOTOX within 2 weeks., compared to only 68% of patients who underwent Lord's procedure. 8% fissures healed between 2 and 4 weeks among Group B, whereas 32% of cases who underwent Lord's procedure had their fissure healed between 2 and 4 weeks, which was longer than time required to heal with BOTOX, and the

Table 3: Comparison of proctoscopy findings

| Proctology findings | BOTOX | Lord's | P-value |
|---------------------|---------|---------|---------|
| | n (%) | n (%) | |
| PF | 21 (84) | 20 (80) | 0.356 |
| A.F | 2 (8) | 3 (12) | 0.319 |
| Both | 2 (8) | 2 (8) | 0.500 |
| S.T | 4 (16) | 4 (16) | 0.500 |

BOTOX: Botulinum toxin-A

Table 4: Sphincter spasm

| Sphincter spasm | BOTOX | Lord's | P-value |
|-----------------|----------|----------|---------|
| | n (%) | n (%) | |
| + | 20 (80) | 18 (72) | 0.254 |
| - | 5 (20) | 7 (28) | |
| Total | 25 (100) | 25 (100) | |

BOTOX: Botulinum toxin-A

difference was statistically significant ($P = 0.017$) at the end of 4 weeks. Thus, fissure healed significantly earlier with injection BOTOX [Table 6].

7. Comparison of the average duration of hospital stay between two groups:

Table 7 shows a comparison of average duration of hospital stay between two groups.

We found that there was a significant difference between the two groups with $P < 0.05$. Hospital stay being longer with Group L [Table 7].

8. Recurrence:

Table 8 compares the post-procedure recurrence between the two groups.

Of 50 patients, the study recurrence was seen among two, in each group. There was no statistical difference between the two groups when compared to recurrence with $P = 0.5$ [Table 8].

DISCUSSION

AF is one of the most common and painful proctologic diseases. Its treatment has long been discussed, and several different therapeutic options have been proposed. While there is little chance of a cure with conservative behavioral therapy, medical treatment with calcium channel blockers, diltiazem, and nifedipine or glyceryl trinitrate had a considerable success rate ranging from 50% to 90%. The use of 0.4% glyceryl trinitrate in

standardized fashion seems to have the best results despite a higher percentage of headache, while the use of botulinum toxin had inconsistent results. Non-responding patients should undergo L.I.S. The risk of incontinence after this procedure seems to have been overemphasized in the past. Only a carefully selected group of patients, without anal hypertonia, could benefit from anoplasty. In the past decades, the understanding of its pathophysiology has led to a progressive reduction of invasive and potentially invalidating treatments in favor of conservative treatment based on anal sphincter muscle relaxation. Despite some systematic reviews, the debate on the single best treatment for CAF still continues.

Through this study we made our sincere efforts to compare chemical sphincterotomy using BOTOX with age-old practiced yet, popular anal dilatation technique among patients with C.A.F with respect to Indian scenario. This study is a prospective study comparing the effects of Lord's procedure with intrasphincteric BOTOX in patients with C.A.F.

Epidemiology

Most common age group involved was 30–40 with a mean age of patient in Group B being 38.64 while the same was 39.28 in Group L; four patients were in 50–60 years of age group, and only two were above 60 years. There was no incidence found in patients below 10–15 years. The results are comparable to Marby *et al.* study where mean age group was found to be 38 ± 13 years. According to Goligher (1984), the disease is usually encountered in young or middle-aged adults. In Udwadia series, maximum incidence was seen in 31–40 years' age group.^[16,26,27]

As regards sex distribution of CAF among patients, there were a total of 28 male patients and 22 female patients in our study with male:female ratio being 1.3:1. The incidence of fissure in males was slightly greater than females. It is confirmed with a study from Bennett and Goligher (1962) which says that AF is equally common

Table 5: Comparison of pain score

| Pain (VAS Score) | Preoperative | 2 week | 4 week |
|----------------------------|--------------|--------|--------|
| BOTOX | | | |
| Mean | 7.40 | 1.32 | 0.00 |
| ±SD | 1.66 | 0.90 | 0.00 |
| P-value (vs. preoperative) | - | <0.001 | <0.001 |
| Lord's | | | |
| Mean | 7.92 | 4.36 | 0.24 |
| ±SD | 1.29 | 0.99 | 0.52 |
| P-value (vs. preoperative) | - | <0.001 | <0.001 |
| P-value (B vs. L) | 0.111 | <0.001 | 0.013 |

BOTOX: Botulinum toxin-A

Table 7: Comparison of average duration of hospital stay between two groups

| Hospital Stay (days) | BOTOX | Lord's | P-value |
|----------------------|-----------|-----------|---------|
| Mean±SD | 0.00±0.00 | 1.52±0.65 | <0.001 |

BOTOX: Botulinum toxin-A

Table 6: Comparison of fissure healing

| Average duration of fissure healing | BOTOX n (%) | Lord's n (%) | P-value |
|-------------------------------------|----------------|-----------------|---------|
| <2 week | 23 (92) | 17 (68) | 0.017 |
| <4 week | 2 (8) | 8 (32) | |
| Total | 25 (100) | 25 (100) | |

BOTOX: Botulinum toxin-A

Table 8: Recurrence

| Recurrence | BOTOX n (%) | Lord's n (%) | P-value |
|------------|----------------|-----------------|---------|
| Yes | 1 (4) | 1 (4) | 0.500 |
| No | 24 (96) | 24 (96) | |
| Total | 25 (100) | 25 (100) | |

BOTOX: Botulinum toxin-A

in the two sexes. Most common fissure to encounter was posterior with only five cases showing anterior C.A.F of 50. Of those five patients, 4 were females with only one male presenting with anterior fissure. This supports the fact that anterior fissures are more common in females as compared to males.

Symptomatology

In our study, the most common presenting complaints were pain (96%), second to follow was constipation (68%), and lowest was bleeding (40%). Of 50 patients in about 70–80%, pain was brought lower by BOTOX injection during their subsequent follow-ups. Improvement in this spasm of I.A.S was also noticed in Group B during 6–8 weeks follow-up. This is comparable to a study by Abcarian reporting almost 100% incidence of pain and bleeding among his patients. The higher incidence of bleeding could be due to the presence of hemorrhoids along with fissure.

We found that 80–85% of patients were having PF, 8–10% had A.F, while 5–8% of patients had both. In this study, posterior midline fissure (80%) was more common than anterior midline fissure (8–12%). It has been observed that posterior fissure is more common in both the sexes, although anterior fissure is common in females comparatively. Both anterior and posterior fissures are common in female sex. This was confirmed by a study from Boulous and Araujo J.G.C.76 (1984) which says that posterior fissure (85.7%) is more common than anterior fissure (14.2%).

Abcarian's study had 90% PF and 7% A.F.

Average duration of presenting complaints was 9 months in Group B, whereas it was 8 months in Group L. All these patients were suffering with C.A.F for longer than 6 months and all these have failed with medical therapy dietary modifications and laxatives/sitz bath. This correlates well with Graham Stewart study where average duration symptoms were over 6 weeks.^[28]

In our study, mean time period for injecting BOTOX into I.A.S was 5.6 min as against 43.6 min for performing Lord's procedure. There was statistically significant difference between the two groups with injection BOTOX requiring less time compared to Lord's procedure ($P < 0.001$). As in this study, we considered time for spinal anesthesia/G.A as well as time required for anal dilatation. BOTOX was injected into I.A.S as O.P.D basis using 26-G needle and tuberculin syringe.

Pre-operative pain scoring was done on V.A.S scale as it is easy to interpret and understand. We found no significant difference among pre-operative pain scores between the two study groups. This adds to the fact that our patient groups were matched for baseline characteristics.

Post-procedure Follow-up

Average duration of fissure healing was within 2 weeks. Fissure healed in 92% of patients receiving BOTOX within 2 weeks, compared to only 68% of patients who underwent Lord's procedure. 8% fissures healed between 2 and 4 weeks among Group B, whereas 32% of cases who underwent Lord's procedure had their fissure healed between 2 and 4 weeks, which was longer than time required to heal with BOTOX, and the difference was statistically significant ($P = 0.017$) at the end of 4 weeks.

Thus, fissure healed significantly earlier with injection BOTOX. However, there was no significant difference in healing of fissure after 6 weeks.

A study conducted by Giral *et al.* showed that the fissures were healed in 70% of patients in the botulinum group and 82% in the surgery group. In both the groups, pain relief was 100%. However, mean duration for fissure healing was 1.5 weeks for intrasphincteric BOTOX injection group and 1.8 weeks for lateral internal sphincterotomy.

Hawley showed healing of fissure by 3 weeks for lords procedure and by 7 weeks for P.I.S.^[29]

Pain relief was significant with Group B compared to Group L. All patients were pain free after 6 weeks of follow-up.

Mean C.C.I.S was compared at the end of 2 weeks, 4 weeks, 6 weeks, and 6 months' follow-up. The scores were higher in Group B as compared to Group L for 1–4 weeks. There was a significant difference between the two groups (P -value [B vs. L] = 0.005). However, there was no significant difference between their scores after 4 weeks, i.e., at the end of 6 weeks and 6 months (P -value [B vs. L] = 0.339). Although the incontinence scores as per C.C.I.S showed more incontinence with BOTOX compared to lords group, the actual score being much less and maximum patients were having good continence as per the definition with occasional incontinence to flatus or feces. This further improved after 4 weeks and no patients had incontinence troubling them beyond 4 weeks of BOTOX treatment. Furthermore, it was comparable to incontinence caused by Lord's before during 2-week follow-up.

Saad and Omer study reported an incontinence rates of 24.3% following Lord's, i.e., M.A.D and 5% following surgical sphincterotomy P.I.S.

Bulous and Araujo *et al.* reported the incidence of 49% with Lords as against 22% with P.I.S.

Only five patients had urinary retention. All these five patients had undergone Lord's procedure under spinal

anesthesia. There was no U.R in Group B. This difference was statistically significant ($P = 0.09$).

It was seen that, of 25 patients receiving BOTOX, 22 (85%) were highly satisfied after treatment compared to Lord's group, where out of 25, only 13 patients (52%) were highly satisfied with Lord's procedure. Further, it can be seen that there is a significant difference between the two groups, and patients were more satisfied with BOTOX.

Only two patients developed recurrence, one in each group, during their 6 months follow-up.

There was no significant difference in recurrence between the two groups.

CONCLUSION

BOTOX is as good as an option, compared to ancient yet routinely practiced Lord's anal dilatation technique for CAF. BOTOX significantly reduces pain in patients with C.A.F as compared to Lord's procedure. BOTOX has definite action in reducing the spasm of I.A.S which is the chief cause of development of C.A.F. Spasm significantly improves with BOTOX compared to Lord's procedure. Fecal and flatus incontinence caused by BOTOX is only temporary, and it usually subsides completely within 4 weeks. There is a significant difference in C.C.I.S during 2–4-week follow-up with incontinence being higher with BOTOX. Although BOTOX group showed higher incontinence scores under 4 weeks, it was only temporary, and it disappears spontaneously after 6 weeks. There was no significant difference in C.C.I.S after 6 weeks–6 months' follow-up. C.C.I.S and P.A.C are exhaustive, yet easy to interpret scoring system for assessment of incontinence. We found the significant difference as regards healing of fissure between the two groups. Fissure healed earlier (<2 weeks) with BOTOX compared to Lord's procedure. No fissure was found beyond 6 weeks in either category.

REFERENCES

1. Griffin N, Acheson AG, Tung P, Sheard C, Glazebrook C, Scholefield JH, et al. Quality of life in patients with chronic anal fissure. *Colorectal Dis* 2004;6:39-44.
2. Gui D, Rossi S, Runfola M, Magalini SC. Review article: Botulinum toxin in the therapy of gastrointestinal motility disorders. *Aliment Pharmacol Ther* 2003;18:1-6.
3. Kodner IJ, Fry RD, Fleshman JW, Birnbaum EH, Read TE. Colon, rectum and anus. In: Schwartz Seymour I, et al. editors. *Principles of Surgery*. 7th ed. New York: Mac Grow-Hill; 1999. p. 1265-382.
4. Lund JN, Scholefield JH. Aetiology and treatment of anal fissure. *Br J Surg* 1996;83:1335-44.
5. Beck DE, Timmcke AE. Pruritus ani and fissure-in-ano. In: Beck DE, editor. *Handbook of Colorectal Surgery*. 2nd ed. New York: Marcel Dekker; 2003. p. 367.
6. Cook TA, Brading AF, Mortensen NJ. The pharmacology of the internal anal sphincter and new treatments of ano-rectal disorders. *Aliment Pharmacol Ther* 2001;15:887-98.
7. Farouk R, Duthie GS, MacGregor AB, Bartolo DC. Sustained internal sphincter hypertonia in patients with chronic anal fissure. *Dis Colon Rectum* 1994;37:424-9.
8. Rattan S, Chakder S. Role of nitric oxide as a mediator of internal anal sphincter relaxation. *Am J Physiol* 1992;262:G107-12.
9. Lund JN. Nitric oxide deficiency in the internal anal sphincter of patients with chronic anal fissure. *Int J Colorectal Dis* 2006;21:673-5.
10. Schouten WR, Briel JW, Auwerda JJ. Relationship between anal pressure and anodermal blood flow. The vascular pathogenesis of anal fissures. *Dis Colon Rectum* 1994;37:664-9.
11. Schouten WR, Briel JW, Auwerda JJ, De Graaf EJ. Ischaemic nature of anal fissure. *Br J Surg* 1996;83:63-5.
12. Kua KB, Kocher HM, Kelkar A, Patel AG. Effect of topical glyceryl trinitrate on anodermal blood flow in patients with chronic anal fissures. *ANZ J Surg* 2001;71:548-50.
13. American Gastroenterological Association. American gastroenterological association medical position statement: Diagnosis and care of patients with anal fissure. *Gastroenterology* 2003;124:233-4.
14. Watts JM, Bennett RC, Goligher JC. Stretching of anal sphincters in treatment of fissure-in-ano. *Br Med J* 1964;2:342-3.
15. Sohn N, Eisenberg MM, Weinstein MA, Lugo RN, Ader J. Precise anorectal sphincter dilatation-its role in the therapy of anal fissures. *Dis Colon Rectum* 1992;35:322-7.
16. Marby M, Alexander-Williams J, Buchmann P, Arabi Y, Kappas A, Minervini S, et al. A randomized controlled trial to compare anal dilatation with lateral subcutaneous sphincterotomy for anal fissure. *Dis Colon Rectum* 1979;22:308-11.
17. Jensen SL, Lund F, Nielsen OV, Tange G. Lateral subcutaneous sphincterotomy versus anal dilatation in the treatment of fissure in ano in outpatients: A prospective randomised study. *Br Med J (Clin Res Ed)* 1984;289:528-30.
18. Nielsen MB, Rasmussen OO, Pedersen JF, Christiansen J. Risk of sphincter damage and anal incontinence after anal dilatation for fissure-in-ano. An endosonographic study. *Dis Colon Rectum* 1993;36:677-80.
19. Renzi A, Bruscianno L, Pescatori M, Izzo D, Napolitano V, Rossetti G, et al. Pneumatic balloon dilatation for chronic anal fissure: A prospective, clinical, endosonographic, and manometric study. *Dis Colon Rectum* 2005;48:121-6.
20. Yucel T, Gonullu D, Oncu M, Koksoy FN, Ozkan SG, Aycan O, et al. Comparison of controlled-intermittent anal dilatation and lateral internal sphincterotomy in the treatment of chronic anal fissures: A prospective, randomized study. *Int J Surg* 2009;7:228-31.
21. Abcarian H. Surgical correction of chronic anal fissure: Results of lateral internal sphincterotomy vs. Fissurectomy-midline sphincterotomy. *Dis Colon Rectum* 1980;23:31-6.
22. Jost WH. Ten years' experience with botulin toxin in anal fissure. *Int J Colorectal Dis* 2002;17:298-302.

23. Jost WH, Schimrigk K. Therapy of anal fissure using botulin toxin. *Dis Colon Rectum* 1994;37:1321-4.
24. Jost WH, Schimrigk K. Use of botulinum toxin in anal fissure. *Dis Colon Rectum* 1993;36:974.
25. Jankovic J, Brin MF. Botulinum toxin: Historical perspective and potential new indications. *Muscle Nerve Suppl* 1997;6:S129-45.
26. Hoffmann DC, Goligher JC. Lateral subcutaneous internal sphincterotomy in treatment of anal fissure. *Br Med J* 1970;3:673-5.
27. Notaras MJ. The treatment of anal fissure by lateral subcutaneous internal sphincterotomy-a technique and results. *Br J Surg* 1971;58:96.
28. Jenkins JT, Urie A, Molloy RG. Anterior anal fissures are associated with occult sphincter injury and abnormal sphincter function. *Colorectal Dis* 2008;10:280-5.
29. Hawley PR. The treatment of chronic fissure-in-ano. A trial of methods. *Br J Surg* 1969;56:915-8.

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