Original Article

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Modified Kenalog Protocol for Anal Fissures; A Quasi Experimental Trial

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Author`s Contribution

[1-4]Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work, Final approval of the version to be published, Drafting the work or revising it critically for important intellectual content, [5]Active participation in active methodology, statistical analysis

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ABSTRACT

Objective: To ascertain the role of triamcinolone injection at the base of an anal fissure and its effect on healing and pain relief.

Methodology: A quasi-experimental study was conducted from November 2021 to February 2022. Under aseptic measures, a 1ml Triamcinolone 40mg/ml injection was administered at the base of the anal fissure using a 1cc insulin syringe. This was injected in four positions around the base of the fissure. Patients were followed for one week to assess pain relief and improvement in quality of life. Patients were assessed for quality of life improvement and satisfaction with treatment. Patients were offered lateral internal sphincterotomy at the end of one week and again on follow up after two weeks given they were not satisfied with pain relief or symptom recurrence occurred.

Results: Twenty five patients were enrolled and analysed. All fissures were seen to have a red inflamed base at enrollment. At one week after treatment, a paler base with less signs of inflammation was observed. Patients reported a mean 70% improvement in their symptoms. A mean change of 16.45 points was seen in Brief Pain Inventory scores at one-week follow up. 25% underwent a lateral internal sphincterotomy. The number needed to treat was 2.5. 5 patients were lost to follow-up after the initial one week follow-up.

Conclusion: Injection of Triamcinolone at the base of an anal fissure may have a role as an adjunct to standard management in treatment. It has been shown to decrease pain and enhance healing of the fissure thus decreasing the need for surgical intervention.

Keywords: Modified Kenalog Protocol; Triamcinolone; Steroid; Anal; Fissure

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Introduction

Anal fissure is a common benign problem encountered in the surgical clinic. It is defined as any longitudinal disruption in the integrity of the epidermis or dermis of the anal canal. This is commonly perceived as a tear in the skin.[1] Local micro-trauma usually from constipation, results in spasm of the internal anal sphincter and an increased anal canal pressure that leads to local ischemia where the fissure develops. This is usually in the posterior anal canal due to relative hypo-perfusion. Ischemia causes difficulty in healing and the spasm persists due to pain. This leads to a cycle of inflammation and non-healing where intervention is required.[1, 2] Typically, extreme pain is experienced while passing stool and may be described as burning lasting hours once it begins.[3] Pain causes avoidance of passing stool and causes constipation, worsening the healing of the fissure.

The management for anal fissures can be divided into operative and non-operative. Operative management generally consists of the gold standard procedure lateral internal sphincterotomy.[2] Non-operative management consists of stool softeners, high fiber diet, topical agents that include Diltiazem cream or GTN cream and analgesics. Botox therapy has also been proven beneficial in the treatment of both acute and chronic fissures.[4] In Pakistan constipation is prevalent amongst all ages and is one of the primary causes of anal fissures, augmented by the fact that the local diet does not support good fiber intake.[5,6] Many novel treatments have been experimented with especially in chronic fissures. One study

experimented with topical diazepam 2% cream and showed some efficacy in pain relief.[7]

Triamcinolone is a synthetic corticosteroid. It exerts potent anti-inflammatory effect by inhibiting cyclooxegenase and lipoxogenase enzymes. These enzymes lead to inflammation and expression of pain as well. Triamcinolone reduces swelling, itchiness, pain and erythema associated with inflammatory responses. It may, at initial administration, cause burning or itching at the area[8]. If steroids are given after the inflammatory response has established, it modulates and decreases inflammation, helping wound healing. Modulation of the inflammatory response also decreases local pain.[9]

The Kenalog Protocol was developed by a colorectal surgeon at Columbia, Dr. Feingold. The procedure entailed a gentle dilatation of the anus with retractors, fissure curettage to stimulate healing, cauterizing the wound as a sealant, and injecting Kenalog into the fissure, under regional anesthesia. Most of his patients were reportedly symptom free within 10 days, while others took over a month. The pilot study[10] of 100 patients published by Dr. Feingold found that 73% of patients were symptom free with the Kenalog protocol as compared to 40-70%[11] of patients that healed with GTN 0.2% alone. The mean time to complete symptom relief was 2.4 weeks, however the maximum number of patients reported 1 week. 13% patients on follow-up that spanned 6 months were found to have recurrent symptoms. 4% of the patients developed a perianal abscess. This was a minimally invasive approach to overcome fecal incontinence issues that may arise from the traditional lateral internal sphincterotomy.[11, 12]

We conducted this study as a continence-preserving approach. We hypothesized that we could decrease the pain and inflammatory response and help local fissure healing by modifying 'The Kenalog Protocol' by injecting triamcinolone at the base of the fissure alongside standard medical therapy without needing curettage or cautery. This would be an inexpensive and novel treatment for anal fissure and would decrease the need for lateral anal sphincterotomy.

Methodology

This was a quasi-experimental study conducted between November 2021 to February 2022. Ethical approval was obtained from the Ethical Committee. The study was conducted in the Department of General Surgery, and follow-up of all patients was done in the outpatient department.

Sample size was calculated using data available from previous studies[11, 13] This was calculated using 73% patients being symptoms free using the Kenalog protocol while another study showed at 2 weeks with conservative treatment, 11.7%[13] of patients were symptom free. The OpenEpi online software was used to calculate the sample size using these percentages, and a minimum sample size of 18 with the Fleiss method was calculated. 25 patients with anal fissures were enrolled by simple convenience sampling. Informed consent was taken from all patients including consent to publish anonymized photographs. All patients who were aged 18-65 and had a peri-anal fissure, both acute and chronic, were included, regardless of the time that the fissure had been present or if they had taken prior treatment or not. Patients were excluded if they had a history of tuberculosis, uncontrolled diabetes, long-standing proctalgia fugax or any identified colorectal pathology that may be causing peri-anal pain. These patients were excluded due to the hypothetical risk of steroid injection exacerbating these diseases or pain from other pathology confounding the results.

At the time of enrollment and at one week follow up patients were asked to fill out a questionnaire. The questionnaire asked for information regarding demographics. Pain scores according to the Visual Analog Score were recorded for all patients on day 1 and day 7. McGill pain description was recorded on Day 1 and Day 7. A quality of life questionnaire; Brief Pain Inventory[14], that included 9 sections asking about daily activity, functionality hindrance due to pain, mood changes due to pain and hindrance in inter-personal relationships, was filled out. All questions were given a numerical score based on a Likert scale ranging from 0-10 where 0 showed no interference due to pain and 10 showed severe interference due to pain. This score was calculated both at the time of enrollment and on day 7 of follow-up. Patients were also asked to subjectively mention what percentage from 0-100% improvement they felt they have experienced after a week of the injection. Patient global impression of change was recorded for all patients on day 7, scored on a Likert scale of 7 points with 4 being no change, 7 being very much worse and 1 being very much improved. All patients were asked to describe if they experienced pain on injection, if they experienced any side effects after the injection and how long the pain lasted. Patients that felt their symptoms

were not improved satisfactorily or had re-appearance of symptoms after two weeks follow up underwent a lateral internal sphincterotomy. All data was entered into SPSS V24 and analysis done using SPSS V24.

Results

Twenty five patients were enrolled into the study. 5 patients did not follow up beyond one week thus need for a lateral internal sphincterotomy could not be established.

60% (n=15) of participants were women and 40% (n=10) participants were male. The mean age of participants was 34.7 SD 7.95 years. The participants had a mean weight of 66.8 SD 8.97 kg.

Participants were asked if they had any known drug allergies, 4% (n=1) had a penicillin allergy and 4% (n=1) had allergy to aspirin. Participants were asked if they had any prior history of surgery. 12% (n=3) had undergone a C-section, 12% (n=3) had undergone an episiotomy, 4% (n=1) had undergone a tonsillectomy.

The majority of our participants were housewives 44% (n=11). 16% (n=4) participants were students, house help 4% (n=1), office clerks 8% (n=2), rickshaw drivers 8% (n=2), teachers 8% (n=2), security guards 8% (n=2) and sweepers 4% (n=1) by profession. 76% (n=19) of our participants were married. 20% (n=5) were current smokers.

None of the participants had any history of tuberculosis active or treated. 12% (n=3) were hypertensives controlled on medication.

The cause of fissure in all participants was constipation. Some patients had taken various treatments and these are enlisted in table I.

Table I: Frequency distribution of various treatments taken by patients.

Treatment	Frequency	(%)
NSAIDs	4	16%
Paracetamol	3	12%
Xylocaine gel and NSAID	2	8%
GTN cream and NSAID	2	8%
GTN cream	1	4%
Tronolone Cream	1	4%
None	12	48%

All fissures were seen to have a red inflamed base at enrollment with various depths and lengths. 88% (n=22) fissures examined at one week after treatment were found to have a paler base with less signs of inflammation, decreased induration and decreased tenderness on palpation of the fissure base. This is shown in image 1. 12% (n=3) were not examined due to inability to follow up in the clinic.

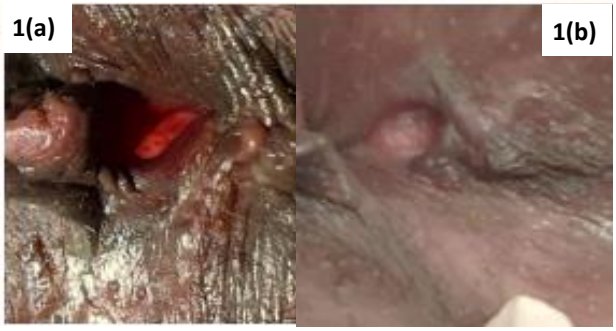

Figure. Image 1a and1b show a before and after picture of an anal fissure following Triamcinolone injection to the base.

1(a). Image taken at enrollment shows a red inflamed base of the fissure with depth of around 1.5cm

1(b). Image taken 1 week after injection of Triamcinolone at the base of the fissure shows paler base and decreased depth of around 0.75cm.

Patients were asked to enumerate numerical pain score during the injection, time till onset of perianal pain after injection, time till resolution of perianal pain after injection and any unpleasant effects experienced after the injection. These are shown in table II.

Table II: Patient experiences and results pertaining to Kenacort injection.

Outcome			N (%)
Numerical Pain score after injection administration		3.40±1.32	-
Time till onset of pain following Triamcinolone injection in hours		0.52±0.18	-
Time from onset till pain resolution after Triamcinolone injection in hours		1.74±0.63	-
Unpleasant experiences following Kenacort Injection	Drowsiness	-	12 (48%)
	Drowsiness and low grade fever lasting less than 48 hours	-	1 (4%)
	Low grade fever lasting less than 48 hours*	-	1 (4%)
	Nausea	-	2 (8%)
	Palpitations	-	5 (20%)

*Low grade fever lasting less than 48 hours: Low grade fever was documented as maximum temperature till 99.8F, associated with a sensation of warmth in the body.

Patients visual analog score was recorded at the time of enrollment and on day seven after Kenacort injection; McGill pain descriptor was recorded on day 1 and day 7; Patient global impression of Change on day 7, Brief Pain Inventory Score on day 1 and day 7; what day of treatment maximum pain relief was achieved and patient reported percentage improvement in symptoms on day 7. These results are shown in table III.

At the end of the study at two weeks follow-up patients were asked about concerns regarding their treatment. 25% (n=5) had a concern that their pain had not fully resolved. No patients complained of incontinence. 20% (n=5) were lost to follow up.

Table III: Patient outcomes on follow-up.

Outcome		**Mean±SD**		**N (%)**
Day maximum relief occurred from pain		5.56±1.12		-
Visual analog score at enrollment		7.48±1.08		-
Visual analog score at day 7		2.52±1.04		-
Difference in visual analog score		4.96±1.06		-
Brief Pain Inventory Score at enrollment		34.4±5.53		-
Brief Pain Inventory Score Day 7		18.6±5.41		-
Difference in Brief Pain Inventory Score		15.88±4.36		-
Patient Global Impression of Change Score on day 7		1.96±0.61		-
Patient reported improvement as a percentage		71±12.3		-
McGill Pain Descriptor at enrollment	Brief	-	-	11 44%)
	Periodic	-	-	8 (32%)
	Continuous	-	-	6 (24%)
McGill Pain Descriptor on Day 7	Brief	-	-	21 84%)
	Periodic	-	-	4 (16%)
	Continuous	-	-	0 (0%)

20 of the patients were followed for 2 to 4 weeks following the injection of Kenacort while 5 patients were lost to follow-up. Of the 20, 25% (n=5) patients opted for a lateral internal sphincterotomy to decrease their discomfort despite improvement in symptoms. Other patients remained satisfied with their treatment progress and did not feel they needed any surgical intervention. 5 patients were lost to follow up after 2 weeks.

A chi-square analysis was done to see if there was a significant difference between the McGill pain descriptor of patients on Day 1 and Day 7 a P-value of 0.40 was obtained showing there was no significant difference.

A paired sample t-test was conducted to see if there was a significant difference between the visual analog pain scores on day 1 and day 7 and Brief Pain Inventory Score on Day 1 and day 7. P-values of 0.01 and 0.001 were obtained for visual analog core and Brief Pain Inventory Score respectively, showing a significant difference existed in both the analyses.

A chi-square analysis was done to see if there was an association between pain score at injection and age or gender. P-value of 0.62 and 0.18 were computed showing no association existed with age or gender and pain experienced at injection.

A bi-variate analysis was done to see if a correlation existed between age and visual analog scores on day 1 and day 7. For visual analog score on day 1 and day 7 Spearmann's Rho was negatively correlated with age showing that with increasing age lower pain scores were experienced both prior to treatment and after treatment.

A chi-square analysis was done to assess if smoking affected the change experienced in pain scores at enrollment and at follow-up, a p-value of 0.63 was obtained showing that smoking does not affect pain relief following Kenacort injection.

An independent sample student T-test was done to see if weight had an association with pain score on day 7 stratified as less than 4 that is mild pain or greater than or equal to 4 that is moderate or severe pain in patients. P-value of 0.70 showed that no significant difference existed between the mean weight of patients with higher and lower pain scores.

A multinomial regression analysis was done to see the factors and co-variates that influence the need for a lateral internal sphincterotomy. Gender, Medication history, smoking status, Age. Weight, Change in visual analog score and Change in Brief pain inventory score were analysed. Cox and Snell pseudo-r^2 value of 0.851 was calculated. The analysed factors had an effect on the variance of outcome in over half the model thus showing that patient factors play a significant role in determining whether lateral internal sphincterotomy may be needed.

Discussion

The Kenalog protocol[10] which was developed to be a sphincter-saving intervention for peri-anal fissure found

that 73% of patients were symptom free after treatment. This involved curettage of the fissure under regional anesthesia, cauterization of the base and injection of triamcinolone at the base. In our study, to decrease the invasiveness of the procedure and to decrease the need for regional anesthesia we simply injected triamcinolone 40mg at the base of the anal fissure and followed the patients to see their change in pain scores, quality of life improvement and the need for a lateral internal sphincterotomy. The need for regional anesthesia was obliterated in our patients as we found that the mean pain at injection was 3.52 and that the pain began on average 30 minutes after injection and lasted for a mean 1.72 hours and was controlled with Paracetamol and Ketorolac intravenously administered in the ward during a short stay. No patients needed to be kept overnight, and all were able to resume their daily activities upon leaving.

In the study done by Feingold et al.[10] 73% of patients reported symptomatic relief. Though none of our patients had 100% symptomatic relief, patients achieved on average a 71% relief from their symptoms. This was encouraging and gave evidence for the use of triamcinolone use alone for pain relief in anal fissures. Most patients in our study stated their pain was much improved. Moreover, in the Kenalog Protocol, patients were symptom free on average at 2.4 weeks with most patients symptom free at 1 week. We found this was reproducible in our study where most patients had improved by the end of the first week and only 20% of patients required further intervention at the end of two weeks. In the original study 13% of patients reported persistent or recurrent symptoms. This was done with a fissurectomy and curettage along with a Kenacort injection to improve healing. In our study, 20% of patients had symptom recurrence, thus showing this was only marginally greater than the original Kenalog protocol. Thus, simple injection of triamcinolone alone at the base of the anal fissure without fisurectomy or curettage may reduce the need for surgical intervention and further it reduces the need for two surgical interventions if the original Kenalog protocol is to be followed.

Four patients had developed perianal abscesses and three developed hemorrhoidal thrombosis following the Kenalog protocol.[10] In our modified Kenalog protocol, this complication was not seen. This may be due to fewer patients and larger trials may be able to address whether this complication is likely occur with triamcinolone injection alone or not. However, we are hopeful that with proper aspetic measures and in certain cases antibiotic prophylaxis this dreaded complication would not arise.

65% of our patients had taken prior treatment and were likely to undergo a lateral internal sphincterotomy, however we found that only 25% of our patients eventually underwent a LIS. This translates to a value of 2.5 numbers needed to treat; that is in every 3 patients that undergo a simple injection of Triamcinolone at the base of the fissure 1 patient is spared the need for a lateral internal sphincterotomy and possible incontinence. Numbers needed to treat less than 5 usually are acceptable and can give evidence from a study off the utility of the treatment.[15] In our study we had an acceptable numbers needed to treat thus perceiving that the intervention may merit further study. This was an important finding as the previous Kenalog protocol study did not incorporate this number and statistical evidence of efficacy was missing.

We found that patients experienced mild side effects, and these were usually self limiting and easily controlled by over the counter medications. As a new experimental technique with no published literature we were keen to enumerate any side effect experienced. Overall, the few side effects as compared to the pain relief and decreased need for a lateral internal sphincterotomy fits a good cost-benefit model.

Patients experienced a clear reduction in pain scores after one week of treatment. However, Triamcinolone injection must be offered as an adjunct with continued topical therapy and stool softeners to obtain maximum benefit.

After one week of intervention, 80% patients experienced only brief pain, which shows that triamcinolone injection also improves the quality of pain. This change makes it easier to bear and carry out normal activities thus improving patient satisfaction and recovery.

We conducted multi-nomial regression analyses to see if patient played a role in determining the need for a lateral internal sphincterotomy. It was found that patient factors did play a role in this outcome. Thus it would be difficult to predict which patient prototype would benefit the most from treatment. However, adjunct treatment with Kenacort at the base of an anal fissure may benefit all patients, even if in varying amounts.

Considering the impact constipation has on our population and affects them at all ages[5, 16] and the resultant distress caused by anal fissures, a simple intervention such as the 'Modified Kenalog Protocol'

may prove to have a beneficial effect as was seen in our study in improving quality of life, decreasing pain and have a sphincter sparing effect.

Larger trials may be conducted to see the effect of triamcinolone local injection at the fissure base and its outcomes based on our study outcomes. Our study was a small quasi-experimental trial and was limited by this however the promising results can be expanded upon. Triamcinolone may find a place in the treatment of healing anal fissures and decreasing the need of surgical intervention and the risk of incontinence.

Conclusion

Simple injection of Triamcinolone at the base of an anal fissure may have a role as an adjunct to standard management in treatment. It has shown to decrease pain and enhance healing of the fissure thus decreasing the need for surgical intervention. This 'Modified Kenalog Protocol' merits larger scale studies to ascertain outcomes and in defining which patient population may benefit the most.

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