

Original Research Article

The role of topical steroids in the treatment of primary pruritus ani: a systematic review

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ABSTRACT

Background: Steroids can alleviate symptoms long enough for the patient to stop the compulsive pruritus-scratch cycle and allow for healing excoriated perianal skin, owing to potent anti-inflammatory and anti-proliferative effects. This systematic review was designed to evaluate the use of topical steroids for the treatment of primary pruritus ani.

Methods: Studies were retrieved after searching the electronic databases Medline, Google Scholar, and Cochrane Central. The search terms, pruritus ani, anal itching, idiopathic pruritus ani, primary pruritus ani and topical steroids were used. Outcomes were efficacy in reduction of pruritus and side-effects.

Results: A total of 7 studies met our inclusion criteria accounting for 181 total of cases of primary pruritus ani treated with topical steroids between 1982 and 2007. On regard of the 181 cases, mean age of patients ranged from 35.4 to 49.5 years old, and similar proportion of males (51.6%) and females (48.4%) was found. Mean duration of symptoms (pruritus ani) varies widely among the studies, with a minimum 5.2 weeks to a maximum 6.5 years. The majority of studies employed hydrocortisone ointment at different concentrations (0.25% and 1%) as the primary therapy. On regard of the overall effectiveness of topical steroid therapy in patients with primary pruritus ani, it ranges between 73.9% to 100%. Few or no side effects were reported in the studies.

Conclusions: This systematic review found a lack of high-quality studies on the efficacy of topical steroids in the treatment of primary pruritus ani.

Keywords: Anal itching, Idiopathic pruritus ani, Pruritus ani, Topical steroids

INTRODUCTION

Pruritus is a very common, unpleasant sensation that elicits an urge to scratch.¹ It was first described by Samuel Hafenreffer in 1660.² Pruritus ani is defined as a dermatologic condition characterized by itching and/or burning in the perianal region or a desire to scratch the anal and perianal skin.⁵ Up to 5% of the population may be affected.³⁻⁶ Men are more commonly affected than women with a 4:1 ratio⁷ and is most commonly present in the fourth to sixth decades of life.^{3,5,7} Pruritus ani is

classified as either primary or idiopathic, and secondary.^{3,5} Pruritus ani is considered primary when no other demonstrable cause can be found,³ and is the most common form of pruritus (50 to 90% of cases).⁸ Pruritus ani is a common complaint seen by primary care physicians, general surgeons, and colorectal surgeons.⁷ The itching sensation can range in severity from mild to extremely intense.⁵

After reassurance, routine therapy and proper anal hygiene, topical steroids could be employed.⁷ Steroids

can alleviate symptoms long enough for the patient to stop the compulsive pruritus-cratch-pruritus cycle and allow for healing excoriated and inflamed perianal skin, owing to potent anti-inflammatory and antiproliferative effects.⁹⁻¹¹ Although steroids are always mentioned in review papers³⁹ and text books as first-line topical therapy, and even considered as one of the most effective regimens for idiopathic pruritus ani, there is an important lack of high quality trials and no systematic reviews or meta-analysis are published in this subject up to date.¹²⁻¹⁴

This systematic review aims to evaluate the use of topical steroids for the treatment of primary pruritus ani, focusing on efficacy and side-effect rates.

METHODS

This systematic review was conducted according to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines.¹⁵ No previous review protocol was published.

Search strategy

The online literature was searched using the following combination of medical subject heading (ME SH) terms “pruritus ani” or “anal itching” or “idiopathic pruritus ani” or “primary pruritus ani and “topical steroids” a medline (using pubmed as the search engine), cochrane database and google scholar search was performed. searches were limited to publications in English, with no limitation on time. titles and abstracts were screened for eligibility and full-text articles were retrieved. The latest electronic search was performed on May 15, 2018.

Eligibility criteria

Original clinical studies evaluating topical steroid therapy for primary pruritus ani were included. We anticipated low number of studies and lack of uniformity regarding disease definition and reporting of results, in consequence we decided to include all published studies regardless of study design. Inclusion criteria included any randomized controlled trial (RCT), prospective descriptive study, retrospective descriptive study, or case series. We excluded review articles and studies with no results available. Manuscripts were excluded if an electronic version was unavailable. Patients with secondary pruritus ani were excluded. In studies with both primary and secondary etiologies of pruritus ani, only patients with primary or idiopathic pruritus ani were included in our study, patients with secondary etiology were eliminated.

Quality assessment

The quality of the articles was assessed using the GRADE (The Grading of Recommendations Assessment, Development and Evaluation) guidelines.¹⁶ Each article was rated on a 4-point scale from high to very low, based on the level of confidence in the effect estimate.

Data collection process and synthesis

Authors independently extracted data from the included studies on a Microsoft Excel database. The following information was recorded: author names, year of publication, journal, type of study, country, number of patients, type of steroid employed, regimen of treatment (dose, duration of treatment), and outcomes (effectiveness, side effects).

Data was presented using descriptive methods. The primary outcome of our study was to determine the effectiveness of topical steroid therapy in itching reduction in patients with primary pruritus ani. Secondary outcome of the study was the presence of side-effects related to steroids.

RESULTS

A flowchart overview of the search is depicted in Figure 1. A total of 7 studies met our inclusion criteria accounting for 181 total of cases of primary pruritus ani treated with topical steroids between 1982 and 2007. Most of the publications originated from the United Kingdom (66.6%). Two small prospective crossover RCT were found.^{10,17} The rest of the studies included were prospective descriptive studies see Table 1.¹⁸⁻²¹ Allenby et al, reported two different studies (one RCT and one prospective descriptive study) in the same paper, for the purpose of this review we analyzed separately each study.¹⁰

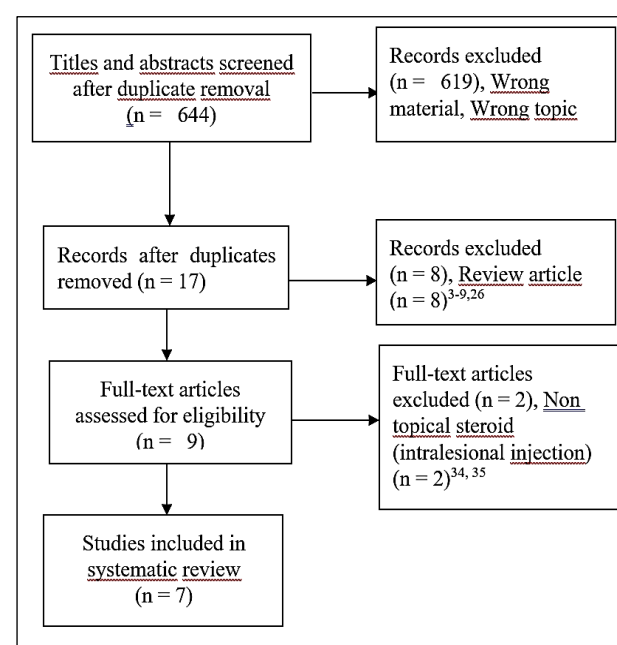


Figure 1: PRISMA flowchart overview.

Patients

On regard of the 181 cases, mean age of patients ranged from 35.4 to 49.5 years old, and similar proportion of

males and females was found (males 51.6% and females 48.4%). Mean duration of symptoms (pruritus ani) varies widely among the studies, with a minimum 5.2 weeks to a maximum 6.5 years.^{10,17-21} Study characteristics and outcomes including efficacy rates and side-effects are shown in Table 2 and 3.

Topical steroid therapy

The majority of studies employed hydrocortisone ointment at different concentrations (0.25% and 1%) as the primary therapy.^{17,20,21}

One study employed steroids in spray (0.2% hydrocortisone) with lignocaine hydrochloride. Oztas et al, evaluated the topical effect of a cream containing methylprednisolone aceponate 0.1% (Table 2).^{10,18} Regimen varies widely between studies, ranging for 1 week period to 4 week period.^{10,20} Two studies evaluated the treatment in a 2-week regime.^{17,18} Dasan et al., employed 30-g tube of steroid ointment and was applied once at night with instruction that the tube should last for 3 to 6 months.²¹

Table 1: Summary of original papers used in this review.

Study	Year	Study type	Population	Total patients (n)	GRADE
Al-Ghnaniem et al ¹⁷	2007	Prospective randomized cross over trial	United Kingdom	10 (cross over)	Moderate
Allenby et al ^{10*}	1993	Prospective randomized cross over trial	United Kingdom	23 (cross over)	Moderate
Oztas et al ¹⁸	2004	Prospective descriptive study	Turkey	60 (28 steroid vs. 32 with liquid cleanser)	Low
Daniel et al ¹⁹	1994	Prospective descriptive study	United States	27	Low
Allenby et al ¹⁰	1993	Prospective descriptive study	United Kingdom	58	Low
Smith et al ²⁰	1982	Prospective descriptive study	United States	32	Very Low
Dasan et al ²¹	1999	Prospective descriptive study	United Kingdom	3	Very Low

GRADE: The Grading of Recommendations Assessment, Development and Evaluation¹⁶

Table 2: Study characteristics.

Study	Mean age (years) / Sex (M/F)	Mean duration of pruritus ani	Drug arms	Regimen
Al-Ghnaniem et al ¹⁷	49.5 y; M: 5; F: 5	50.2 months	1% hydrocortisone ointment vs. placebo	2-week period 14 d washout
Allenby et al ^{10*}	48.8 y; M: 9; F: 14	NR	0.2% hydrocortisone spray vs. placebo	1-week period 7 d washout
Oztas et al ¹⁸	35.4 y; M: 16; F: 12	NR	Steroid cream (methylprednisolone 0.1%) vs. Liquid cleanser	2-week period
Daniel et al ¹⁹	52.1 y; M: 16; F: 11	5.2 weeks	Steroid creams (non-specified)	No specified
Allenby et al ¹⁰	45.9 y; M: 29; F: 29	NR	0.2% hydrocortisone spray	4-week period
Smith et al ²⁰	NR; M: 62; F: 13	6.5 years	Steroid ointments (1% and 0.25% hydrocortisone)	1-week period
Dasan et al ²¹	42 y; M: 2; F: 1	3 years	Steroid ointment (1% hydrocortisone or Clobetasol propionate)	30-g tube for 3-6 months

M: Male; F: Female; NR: Not reported in the study; *prospective cross over trial

Assessment and efficacy of topical steroid therapy

There is no standard way of reporting outcomes of treatment of pruritus ani. This interfere with comparison of results among approaches and among institutions (Table 3). The most widely way to report effectivity of topical steroids among studies was describing reduction

of pruritus with a visual analogue scale.^{10,17} Other studies evaluated effectivity of the topical steroids asking directly to the patients if they considered that the pruritus has improved.¹⁹⁻²¹ Oztas et al., assessed with a 0-10 score of pruritus (0: no pruritus, 10: the most severe pruritus).

Al-Ghaniem and his group, reported their outcomes with topical steroids after 2-week of follow-up during which the patients filled a daily VAS for the severity of itch (0-100 mm) and a weekly Dermatology Life Quality Index (DLQI) questionnaire (0-30 points).¹⁷ At the end of the treatment the patients were evaluated with the Eczema Area and Severity Index (EASI) score (0-12 points). On regard of the overall effectiveness of topical steroid therapy in patients with primary pruritus ani, it ranges between 73.9% to 100%.^{10,21}

Treatment with 1% hydrocortisone ointment resulted in a 68% reduction in VAS compared with placebo (P =

0.019), a 75% reduction in DLQI score (P = 0.065), and 81% reduction in EASI score (P = 0.01) in a RCT.¹⁷

Side effects

Two studies did not found complications after treatment with topical steroids.^{17,18} Three studies did not provide evaluation or information about side-effects.¹⁹⁻²¹

Only Allenby et al, reported the following side effects: slight transient stinging (17.4%), irritation (3.4%) and dryness (1.7%) after steroid topical therapy. And all side-effects were local, few, minor and transient.¹⁰

Table 3: Summary of effect of topical steroid on pruritus ani.

Study	Primary outcome (effectiveness)	Other study outcomes	Complications related to treatment
Al-Ghaniem et al ¹⁷	68% Reduction of pruritus in VAS (p = 0.019)	75% reduction in DLQI (p = 0.067) 81% reduction in EASI (p = 0.01)	No side effects
Allenby et al ^{10*}	Effective treatment n = 17/23 (73.9%)	Similar to placebo n = 4/23 Preference for placebo n = 2/23	Transient stinging n = 1/23
Oztas et al ¹⁸	Effective treatment with steroids 92.3%	Liquid cleanser effectiveness 90.6%	No side effects
Daniel et al ¹⁹	Initial improvement n=27/27 (100%)	Recurrence of pruritus n=6/27	Not reported
Allenby et al ¹⁰	Effective treatment n = 46 /58 (79.3%)	Partially effective n = 4/58 Ineffective n = 2/58 Withdrawn n = 4/58 Lost to follow up n = 2/58	None n = 36/58 Slight transient stinging n = 10/58 Irritation n = 2/58 Dryness n = 1/58
Smith et al ²⁰	Good results n = 24/32 (75%)	Bad results n = 8/32	Not reported
Dasan et al ²¹	Resolution of symptoms n = 3/3 (100%)		Not reported

VAS: visual analogue scale; DLQI: Dermatology Life Quality Index; EASI: Eczema Area and Severity Index; *prospective cross over trial

The maximum dose and the maximum safe duration of topical perianal steroids were not de-scribed. Although inconsistency in reporting side-effects, all authors mentioned the potencial side effects of using long-term steroids and suggested a short-term use.^{10,17,21}

DISCUSSION

The pathophysiology of itching is thought to be related to the C-fibers in the skin.⁹ C-fibers are slow-conduction velocity unmyelinated fibers with extensive terminal branches and transmit mes-sages that the brain interprets as the sensation of itch.³ Histamine, kallikrein, papain, trypsin, and bradykinin have been implicated in itching.^{9,12} Scratching to relieve pruritus can cause further damage (excoriation) and inflammation, which induces additional stimuli of the C-fibers.⁹ Scratching is thought to produce inadequate feedback to inhibit further itching.¹² This cycle is difficult for patients to break.

Any factor that leads the perianal area to become moist, soiled or irritated has the potential induce pruritus.³ Soiling is a contributing factor and perianal fecal contamination can lead to pruritus ani.²² Leakage of mucus and liquid stool macerates the skin and results in burning or itching.²⁰ Exaggerated rectoanal inhibitory reflexes, some degree of incontinence producing fecal soiling, and loose stools are some of the factors related to the pathophysiology of primary pruritus ani.^{3,23-25}

Patients afflicted with pruritus ani have chronic symptoms and a long list of prescribed or over-the-counter treatments.¹² Persistent or chronic pruritus ani could be a socially embarrassing condi-tion.²¹ Coexisting anorectal, infectious or neoplastic pathology must be ruled out with anoscopy, cultures or biopsies.^{3,9} Primary pruritus is diagnosed when no specific pathology after exhaustive examinations is found. A clinical staging system has been developed by the Washington Hospital Center: stage 0 is normal skin; 1 is erythematous,

inflamed skin; 2 is lichenified skin; and stage 3 is lichenified skin with erosions and ulcerations.^{12,13}

The first step in the treatment of primary pruritus ani is reassurance to the patient that there is no underlying malignant or severe disease.^{12,20} Perianal hygiene is thought to be important and is considered to improve symptoms.²⁶ Keeping the area clean by washing, the area dry using towels or soft paper, avoiding soap or shower gel, avoiding sweating by wearing cotton undergarment and avoiding tight clothing and not using talcum powder are essential for maintaining perianal hygiene before applying topical steroids.¹⁷ Control of seepage or leakage with either fiber or anti-diarrheal agents removes an offending agent and makes anal hygiene easier.³ Of paramount importance is to stop scratching in order to break the vicious itching cycle.²⁶

After proper anal hygiene is assured, topical steroid therapy is a safe and effective treatment option.^{3,12} Steroids are the most powerful tool for treating inflammatory skin diseases.²⁷ Itch can also be clinically improved with the use of topical corticosteroids, through the inhibition of inflammatory processes.²⁷ Steroids suppress inflammation by increasing production of anti-inflammatory proteins (like the inhibitor of NF- κ B), suppress production of cytokines involved in chemotaxis and adhesion, and decrease the survival of inflammatory cells.²⁸ In a 2011 study, Sekine et al.,²⁷ described for the first time that corticosteroids suppressed the scratching behaviors induced by all pruritogenic agents (histamine, serotonin, substance P, and PAR-2 agonist).

Only one study found in this review objectively assessed the effectiveness of topical steroids on skin changes using the EASI score. They reported 81% reduction of the EASI score that implies complete reversal of perianal inflammatory skin changes associated to pruritus.¹⁷

Treatment with low-potency topical steroid (e.g., 1% hydrocortisone) is the first-line therapy but should not be given for more than 8 weeks. The majority of patients with mild-to-moderate symptoms and minimal skin changes will respond well to topical steroids applied morning and night after washing.^{6,12} As previously mentioned, published articles considered topical steroids an effective therapy for breaking the itch-injury cycle.³ We found in this review that the overall effectiveness of topical steroid therapy in patients with primary pruritus ani ranges between 73.9% to 100%.²¹

In patients with mild symptoms, once symptoms regress, steroids could be substituted by a barrier cream. In patients with moderate-to-severe symptoms and skin changes, stronger topical steroids are needed, and once the skin heals, switch to a lower potency topical steroid. The maximum safe duration of topical perianal steroids has not been described.⁶ While it seems that topical corticosteroids are effective in the treatment of pruritus,

the wide range of adverse effects, both local and systemic, is not well elucidated.²⁸

As we described in the results section few studies found and described adverse outcomes after using corticosteroids, but all the authors recommended careful use of topical steroids and avoidance of long-term application.

Several local side effects are described after using topical steroids.²⁸ The anus and perianal skin seem to be more prone to complications. Topical steroids, especially when used for long period, can cause atrophy, bacterial and fungal infections, allergic contact dermatitis, telangiectasia, purpura, hypo-pigmentation and/or scar formation.^{11,18} Skin atrophy is a common side effect and presents as increased transparency, shininess and striae.¹¹ Dermal atrophy is probably caused by decreased fibroblast growth and reduced synthesis of collagen and acid mucopolysaccharides.^{11,27} Steroids also stimulate dermal microvascular endothelial cells which produces telangiectasia.²⁸ Contact dermatitis may produce worsening of skin (perianal) disease, non-fluorinated corticosteroids (hydrocortisone, budesonide) are more likely to cause a contact hypersensitivity.^{11,28} Also, mucocutaneous infections are common during treatment with steroids. The corticosteroids suppress inflammation, while the fungal or bacterial growth flourishes.¹¹

Although several potential side effects after topical corticosteroids therapy none of the studies included in this review reported the presence of these complications.^{10,17-21}

For the subgroup of patients who are refractory to topical steroids or patients with side effects related to steroids, a different therapeutic strategy is needed.¹⁷ Another alternative topical therapies used for the treatment of pruritus ani are: topical capsaicin, and tattooing with methylene blue. Capsaicin, has been suggested as a treatment of pruritus.⁹ In 2003, Lysy et al., published a randomized placebo controlled, crossover study of topical capsaicin (0.006%) for idiopathic intractable pruritus ani, and they found it effective.²⁹

For refractory cases of primary pruritus ani, intradermal and subcutaneous injection of the perianal area with methylene blue has been described in case series.³⁰⁻³³ It has been shown to achieve effective control of pruritus ani in 88% of patients who have failed to respond to standard dermatological, hygiene, and surgical treatments.³¹

The main limitation of this review is the generally poor quality of papers reviewed. Another limitation is the heterogeneity among studies, either in assessing and reporting outcomes. Due to the wide variability among studies no comparison of outcomes between them was possible. Another important limitation is the lack of new studies, being the most recent article the one that was

published in 2007. There is a lack of high quality data on regard of the preferred topical perianal steroid preparation (weak vs. strong steroids, and ointments vs. creams), the preferred and maximum dose, and the maximum safe duration of therapy. Despite these limitations, we considered necessary to review this subject because of the relative high frequency of pruritus ani among population, and the popularity of topical steroids use among patients and colorectal surgeons, in addition to the lack of a previously reported systematic review.

CONCLUSION

This systematic review found a lack of high quality studies on the efficacy of topical steroids in the treatment of primary pruritus ani. Also, a lack of a standardized report of outcomes was found. Although it seems that topical steroid therapy is a safe and effective treatment of patients with primary pruritus ani there is no definitive evidence to support this statement. It seems that the best utility of topical steroids is the breaking of the compulsive pruritus-scratching-pruritus cycle by its anti-inflammatory effect. Although several potential side-effects of topical steroids exist, only one study reported minor side-effects. Due to the lack of high quality studies and heterogeneity on the report of results, large prospective randomized controlled trials are needed to define the definitive role of topical steroids in the treatment of primary pruritus ani.

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