

Clinical audit of National Institute of Clinical Excellence (NICE) Technology Appraisal Guidance (TAG) 81 and 82/Clinical Guidelines (CG57) on atopic eczema in children

Mansoor Dilnawaz, Zafar Iqbal Sheikh

Department of Dermatology, Military Hospital, Rawalpindi

Abstract *Objective* To find out how far our current practice complies with the NICE guidelines and to identify any areas in which improvement is needed

Patients and methods The audit sample consists of 50 patients. The inclusion criteria include children from birth up to the age of 12 years and diagnosed with atopic eczema

Results 100% patients (n=50) in this audit were treated with topical corticosteroids. 100% cases (n=50) were treated in accordance with NICE recommendations. The drug with lowest acquisition cost was prescribed in 31 (62%) cases. None of the 50 patients was prescribed either tacrolimus or pimecrolimus.

Conclusions The patients in this audit tended to be young. All patients had either mild to moderate eczema with no cases with severe eczema. All patients responded to treatment regimen comprising topical steroids with none requiring topical calcineurin inhibitors i.e. tacrolimus and pimecrolimus.

Key words

Atopic eczema, topical corticosteroids, topical calcineurin inhibitors, tacrolimus, pimecrolimus.

Introduction

Atopic eczema (atopic dermatitis) is a chronic inflammatory itchy skin condition that develops in early childhood in the majority of cases. It is typically an episodic disease of exacerbation (flares, which may occur as frequently as two or three per month) and remissions, except for severe cases where it may be continuous. Certain patterns of atopic eczema are recognized. In infants, atopic eczema usually involves the face and extensor surfaces of the limbs and, while it may involve the trunk, the napkin area is usually spared. A

few infants may exhibit a discoid pattern (circular patches). In older children flexural involvement predominates, as in adults.

The guidance on the “frequency of application of topical corticosteroids for atopic eczema” (TAG081) and “tacrolimus and pimecrolimus for atopic eczema” (TAG082) were published in August 2004 and reviewed in December 2007 (CG57).¹

TAG081 relates to the frequency of application of topical corticosteroids in the treatment of atopic eczema and does not include the use of topical agents that combine corticosteroids with other active agents (for example, antimicrobials or salicylic acid). It is recommended that topical corticosteroids² for atopic eczema should be prescribed for application only once or twice daily.

Address for correspondence

Dr. Mansoor Dilnawaz
Consultant Dermatologist
Department of Dermatology
Military Hospital (MH), Rawalpindi
Email: mdilnawaz@gmail.com
Tel: 0342-4210568

Where more than one alternative topical corticosteroid is considered clinically appropriate within a potency class, the drug with the lowest acquisition cost should be prescribed, taking into account pack size and frequency of application.

TAG082 relates to topical tacrolimus and pimecrolimus³ and states that they are not recommended for the treatment of mild atopic eczema or as first-line treatments for atopic eczema of any severity. However, topical tacrolimus is recommended, within its licensed indications, as an option for the second-line treatment of moderate to severe atopic eczema in adults and children aged 2 years and older that has not been controlled by topical corticosteroids where there is a serious risk of important adverse effects from further topical corticosteroid use, particularly irreversible skin atrophy.

The guidance further recommends that pimecrolimus is used within its licensed indications as an option for the second-line treatment of moderate atopic eczema on the face and neck in children aged 2 to 16 years that has not been controlled by topical corticosteroids where there is a serious risk of important adverse effects from further topical corticosteroid use, particularly irreversible skin atrophy.

For the purposes of this guidance, atopic eczema that has not been controlled by topical corticosteroids refers to disease that has not shown a satisfactory clinical response to adequate use of the maximum strength and potency that is appropriate for the patient's age and the area being treated.

The guidance also recommends that treatment with tacrolimus or pimecrolimus³ be initiated only by physicians (including general practitioners) with a special interest and experience in dermatology, and only after

careful discussion with the patient about the potential risks and benefits of all appropriate second-line treatment options.

This project plan outlined the minimum requirement for audit as suggested within the guidance, however should individual clinicians wish to expand the focus of the project to examine practice in greater details this should be agreed at relevant specialty audit groups ensuring all clinicians involved in delivering the service are included.

Patients and methods

50 case-records of patients with atopic eczema were selected at random. The inclusion criteria included patients aged 2 years and over and diagnosed with atopic eczema. The method of data collection was retrospective. The basis of proposal was NICE guidelines on atopic eczema. The audit type was Process. The samples sources were case-notes. The sample size was 50 case-records. The sample covered around three month period. A data collection pro forma (**Table 1**) was used. The collected data was analyzed according to the pre-set criteria and standards.

Standards (Table 2)

1. NICE Technology Appraisal Guidance 81 and 82/ Clinical Guidelines CG57.
2. TA081 - Frequency of application of topical corticosteroids for atopic eczema.
3. TA082 - Tacrolimus and pimecrolimus for atopic eczema.

Results

100% patients (n=50) were treated with topical corticosteroids. 100% cases (n=50) were treated in accordance with NICE recommendations (**Table 3**). The drug with lowest acquisition cost was prescribed in 31

Table – 1: Data Collection Pro forma
TAG 081 Frequency of application of topical corticosteroids for atopic eczema

Patient ID.....		Patient D.O.B/...../.....	
1.	Was patient treated with topical corticosteroids for atopic eczema?	Yes	No
Atopic eczema an itchy skin condition in the past 12 months plus three or more of the following: history of flexural involvement (affecting the bends of the elbow or behind the knees); history of a generally dry skin; personal history of other atopic disease (in children younger than 4 years, history of atopic disease in a first-degree relative may be included); visible flexural dermatitis as defined by a photographic protocol; and onset before the age of 2 years (not used in children younger than 4 years).			
2.	Was patient treated in accordance with NICE recommendations?	Yes	No
Topical corticosteroids for atopic eczema should be prescribed for application only once or twice daily .			
3.	Was the drug with lowest acquisition cost prescribed (Name of Drug here)?	Yes	No
*Clinicians will need to agree locally on how the lowest acquisition cost is determined for audit purposes, taking into account pack size and frequency of application.			
4.	If no give details of treatment regime prescribed		

TAG 082 Tacrolimus and pimecrolimus for atopic eczema

Use of Tacrolimus

5.	Describe severity of patient's condition	Mild	Moderate	Severe
Clinicians will need to agree locally how to identify moderate or severe atopic eczema				
6.	Was patient prescribed Tacrolimus?	Yes	No (go to Q 10)	
7.	Has patient's condition been treated previously with topical corticosteroids?	Yes	No	
8.	If yes, (to Q7) did topical corticosteroids control the patient's condition?	Yes	No	n/a
"Not controlled by topical corticosteroids" - disease that has not shown a satisfactory clinical response to adequate use of the maximum strength and potency appropriate for the patient's age and the area being treated.				
9.	If yes (to Q7) was there a serious risk of important adverse side effects from further use of topical corticosteroids?	Yes	No	n/a
"Important adverse side effects" - particularly irreversible skin atrophy which includes telangiectasia, increased transparency and shininess of the skin and the appearance of striae.				

Use of Pimecrolimus

10.	Did patient have Atopic eczema on the face/neck area?	Yes	No	
11.	Has patient's condition been treated previously with topical corticosteroids?	Yes	No	
12.	If yes, (to Q11) did topical corticosteroids control the patient's condition?	Yes	No	n/a
13.	If yes (to Q11) was there a serious risk of important adverse side effects from further use of topical corticosteroids?	Yes	No	n/a
"Important adverse side effects" - particularly irreversible skin atrophy which includes telangiectasia, increased transparency and shininess of the skin and the appearance of striae.				

All patients treated with either Tacrolimus or Pimecrolimus

14.	Was patient treated with Tacrolimus and/or Pimecrolimus?	Tacrolimus	Pimecrolimus	Both
15.	Name of physician initiating treatment			
16.	Was there documentary evidence (in the case notes) of discussion with patient regarding the risks and benefits of all appropriate second line treatments?	Yes	No	
Clinicians will need to agree locally on how the discussion with the patient is documented, for audit purposes.				

Table -2: Standards

TAG 081	
Frequency of application of topical corticosteroids for atopic eczema	
1.	100% of people treated with topical corticosteroids for atopic eczema should be prescribed for application once or twice daily.
2.	Where there is more than one appropriate topical corticosteroid, 100% of people prescribed topical corticosteroids for atopic eczema should be prescribed the drug agreed to have the lowest acquisition cost (<i>once agreed, the name of the drug, can be used to amend the wording of this standard</i>).
TAG 082	

Tacrolimus and pimecrolimus for atopic eczema	
1.	Topical tacrolimus and pimecrolimus should not be prescribed for the treatment of mild atopic eczema or as first-line treatments for atopic eczema of any severity.
2.	Topical tacrolimus should be considered for 100% of adults and children aged 2 years and older with moderate or severe atopic eczema if: ➤ The patient's condition has not been controlled by topical corticosteroids and ➤ There is a serious risk of important adverse side effects from further use
3.	Pimecrolimus should be considered for 100% of adults and children aged 2 to 16 years with moderate atopic eczema on the face or neck if: ➤ The child's atopic eczema has not been controlled by topical corticosteroids and ➤ There is a serious risk of important adverse side effects from further use
4.	In 100% of cases, treatment with tacrolimus or pimecrolimus should be initiated by a physician with a special interest and experience in dermatology.
5.	In 100% of cases, treatment with tacrolimus or pimecrolimus should be initiated after careful discussion between the prescribing physician and the patient regarding the risks and benefits of all appropriate second line treatment options.

Table 3 Results

Q1. Was patient treated with topical corticosteroid for atopic eczema?	n=50
Yes	50 (100%)
Q2. Was patient treated in accordance with NICE recommendations?	n=50
Yes	50 (100%)
Q3. Was the drug with lowest acquisition cost prescribed?	n=50
Yes	31 (62%)
No	19 (38%)
Q4. If no give details of treatment regimen prescribed	n=19
1% Hydrocortisone ointment face + mometasone furoate ointment OD to trunk & limbs	2 (10%)
1% Hydrocortisone ointment to face + mometasone furoate ointment OD to body	3 (15%)
1% Hydrocortisone ointment to face + mometasone furoate ointment OD to trunk	1 (5%)
1% Hydrocortisone ointment to face + mometasone furoate ointment OD to body	1 (5%)
Mometasone furoate ointment OD to trunk	1 (5%)
Mometasone furoate ointment OD to limbs	1 (5%)
Mometasone furoate ointment OD to limbs	1 (5%)
Mometasone furoate ointment OD to perianal region	1 (5%)
Mometasone furoate ointment OD lesions to trunk and limbs + 1% hydrocortisone ointment to face	1 (5%)
Mometasone furoate ointment OD to hands	1 (5%)
Mometasone furoate ointment OD trunk + limbs	1 (5%)
Mometasone furoate ointment OD to limbs	1 (5%)
Mometasone furoate ointment OD to body	2 (10%)
Mometasone furoate ointment OD to body	2 (10%)
Q5 Details of tacrolimus prescribed	n=50
Tacrolimus prescribed in these 50 patients	0 (0%)
Q6 Details of pimecrolimus prescribed	n=50
Pimecrolimus prescribed in these 50 cases	0 (0%)

(62%) cases. None of the patient was prescribed either tacrolimus or pimecrolimus.

Discussion

Atopic eczema (often called atopic dermatitis) is one of a group of related, inherited

conditions that also includes asthma and hay fever⁴. It can make the skin dry, itchy, red, broken and sore. It sometimes makes the skin darker or lighter for a while. People of all ages can get atopic eczema, but it usually starts in early childhood. It usually improves with age, but some people will have the condition into

adulthood.⁵

This guideline covers the management of atopic eczema in children from birth up to the age of 12 years,¹ and provides guidance on diagnosis and assessment, management, and providing information and education for children and their parents and carers. The patients in this audit tended to be young. All patients had either mild to moderate eczema with no cases with severe eczema. All patients responded to treatment regimen comprising topical steroids with none requiring topical calcineurin inhibitors³ that is tacrolimus and pimecrolimus. These are second-line treatments for atopic eczema with appropriate indications. The details of these topical

calcineurin inhibitors prescribing therefore could not be assessed.

References

1. Management of atopic eczema in children from birth up to the age of 12 years. NICE clinical guidelines, CG57 – Issued: Dec 2007.
2. Atherton DJ. Topical corticosteroids in atopic dermatitis. *BMJ*. 2003;**327**:942-3.
3. Breuer K, Werfel T, Kapp A. Safety and efficiency of topical calcineurin inhibitors in the treatment of childhood atopic dermatitis. *Am J Clin Dermatol*. 2005;**6**:65-77.
4. Ahuja A, Land K, Barnes CJ. Atopic dermatitis. *South Med J*. 2003;**96**:1068-72.
5. Eichenfield LF, Lucky AW, Boguniewicz M *et al*. Consensus conference on pediatric atopic dermatitis. *J Am Acad Dermatol*. 2003;**49**:1088-95.