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COMPARISON OF LINSEED OIL VS ZINC OXIDE IN PREVENTING PERISTOMAL EXCORIATION IN PEDIATRIC SURGERY; A RANDOMIZED TRIAL

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Abstract

Introduction: *Peristomal excoriation is the common complication after stoma formation due to the effluent of stoma leading to breakdown of skin. This lead to pain and bleeding and decreases quality of life of the patient. Many agents have been used for management of Peristomal excoriation. Zinc oxide is considered as standard for managing Peristomal excoriation but because of its cost and synthetic nature, a search for better or equally effective natural agent in going on. Linseed oil has been used for multiple purposes since ancient times and it has good effects on skin. This study is conducted to see the outcome of linseed oil by comparing it with zinc oxide for prevention of excoriation around stoma.*

MATERIALS AND METHOD:

Study Design *It is a Randomized Trial (parallel type), registered on TCTR with registration number (TCTR20250222002).*

Methodology: *A total of 120 patients (60 in each group) with stomas due to various diseases were included in study using Balloting method .Data analyzed with SPSS 25 with chi-sqaure test for qualitative and independent sample t-test for quantitative analysis.patients were followed after the 1st week, 3rd week and 6th week to see effects and results were compared*

Place of Study: *carried out at pediatric surgery department in the Children's Hospital and the University of Child Health,Lahore w.e.f 25/08/2022 till 24 /08/2023.*

Objective: *To evaluate the outcomes of linseed oil vs zinc oxide over a one-year period.*

Results: *On the 1st week, 3rd week and 6th week follow up, linseed oil showed comparable results with zinc oxide. On 1st week follow up, linseed oil prevented excoriation in 66.7%whereas zinc oxide prevented excoriation in 75% of patients (p-value 0.308). On 3rd week and 6th week follow up, linseed oil prevented Peristomal excoriation in 20% of patients as compared to 26.7% with zinc oxide.*

Conclusion: *Peristomal excoriation is a common issue in patients after stoma formation. It decreases the quality of life and health of a patient. Linseed oil is a cheap agent which is easily available and is near to standard care in preventing Peristomal excoriation.*

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Introduction:

Peristomal excoriation is defined as any problem of Peristomal skin including erosion or ulceration or dermatitis that is adjacent to stoma. More than half of patients with ileostomy in the pediatric age group have Peristomal skin excoriation and additional therapy is required for Peristomal skin [1]. It is more common with ileostomy due to liquid contents and digestive enzymes which damage the epithelium of skin. It impairs adhesion of the pouching system which in turn exacerbates the skin problem. The principle of prevention of Peristomal excoriation involves minimizing the direct contact of stoma contents with the skin. It involves proper application of pouching system, maintenance of Peristomal hygiene, prevention of infection etc. Various remedies have been used for prevention of skin excoriation traditionally zinc oxide-based creams, lotions and lubricants are used [2-4].

Linseed oil is obtained from flax plant linum ustitatismum also known as alsi which is a member of lineacea family. It is drained from their ripe seeds after drying them. It contains a high amount of alpha linoleic acid (ALA) and omega 3 polyunsaturated fatty acid. After degradation, its metabolites have properties which help prevent inflammation and skin excoriation [5]. The linseed oil forms a base of hydrophobic layer on skin after exposure with stoma contents which further protects against excoriation. It is traditionally used for treatment of perianal rashes in rural areas [6]. This study is done to compare the effects of linseed oil with zinc oxide.

MATERIALS AND METHODS

This randomized controlled trial is carried out in pediatric surgery department, the Children's Hospital and University of Child Health Sciences, Lahore. The duration of study was 12 months after the approval of synopsis w.e.f 25/08/2022 till 24/08/2023.A total of 120 patients were included in this study, 60 in each group. Non-probability Purposive sampling technique was used for enrollment of the patients. Patients were randomly allocated into both groups by balloting method. Patients age less than 14 years, both male and female, having stoma (Ileostomy both loop and divided)due to any reason including NEC, intussusception etc. were included in this study.Data analyzed with SPSS 25 with chi-sqaure test for qualitative variables and independent sample t-test for quantitative variables.All the patients were regularly followed in the outpatient department for any complications for the next 6 weeks (1st week, 3rd week, 6th week).

Results:

A total of 120 patients were included in this study (60 in each group). In the linseed oil group, the mean age was 25.45 months while in the zinc oxide group was 33.98 months. In the linseed oil group, 45 were male and 15 were female patients while in zinc oxide group, 38 were male and 22 were female patients. The mean weight of the patients in the linseed oil group was 8.89 kg while in the zinc oxide group was 11.23 kg. Linseed oil group had more patients of necrotizing enterocolitis (25%) followed by intussusception (15%) while zinc oxide group had more patients of intussusception (18%) followed by enteric perforation (15%).

In the 1st week follow up, in the linseed oil group, 66.7% patients had no excoriation, 33.3% patients had 1st degree excoriation while no patient had 2nd degree excoriation. Whereas in the zinc oxide group, 75% had no excoriation, 23.3% had 1st degree and 1.67% patients had 2nd degree excoriation.

In the 3rd week follow up, in the linseed oil group, 40% patients had no excoriation, 45% patients had 1st degree excoriation while 15% patients had 2nd degree excoriation. Whereas in the zinc oxide group, 53.3% had no excoriation, 36.7% had 1st degree and 10% of patients had 2nd degree excoriation.

In the 6th week follow up, in the linseed oil group, 40% patients had no excoriation, 35% patients had 1st degree excoriation while 25% patients had 2nd degree excoriation. Whereas in the zinc oxide group, 53.3% had no excoriation, 30% had 1st degree and 16.7% of patients had 2nd degree excoriation.

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Table No. 1

Sr. No.	Variable	Sub variable	Linseed Oil	Zinc Oxide	Total
1.	Mean Age		25.45 months	33.98 months	
2.	Gender	Male	45(75%)	38(63.33%)	83(69.2%)
		Female	15(25%)	22(36.67%)	37(30.8%)
		Total	60(100%)	60(100%)	120(100%)
3.	Weight		8.89kg	11.23kg	
4.	Disease	ARM	3 (5%)	0	3(2.5%)
		NEC	15(25%)	8(13.3%)	23(19.2%)
		Intussusception	9(15%)	11(18.3%)	20(16.6%)
		TB	1(1.6%)	4(6.6%)	5(4.2%)
		enteric perforation	3(5%)	9(15%)	12(10%)
		meconium ileus	3(5%)	3(5%)	6(5%)
		atresia	6(10%)	3(5%)	9(7.5%)
		Meckel	8(13.3%)	2(3.3%)	10(8.3%)
		others	12(20%)	20(33.3%)	32(26.7%)
		Total	60(100%)	60(100%)	120(100%)

Table No. 2

Degree of Excoriation								
Sr. No	Follow up	Linseed Oil			Zinc Oxide Paste			Total
		0 degree	1st degree	2nd degree	0 degree	1st degree	2nd degree	
1.	1st week	40 (66.7%)	20 (33.3%)	0	45 (75%)	14 (23.3%)	1 (1.6%)	120(100%)
2.	3rd Week	24 (40%)	27 (45%)	9 (15%)	32 (53.3%)	22 (36.7%)	6 (10%)	120(100%)
3.	6th week	24 (40%)	21 (35%)	15 (25%)	32 (53.3%)	18 (30%)	10 (16.7%)	120(100%)

Discussion:

The results in our study showed that both groups were comparable with respect to age, gender, weight and disease spectrum for which stoma were made. In terms of grading of excoriation on 1st week, 3rd week and 6th week follow up visits, both groups were comparable and no statistically significant difference was found between linseed oil application and zinc oxide in prevention of Peristomal excoriation. However, excoriation prevention was observed in more patients having zinc oxide applications as compared to linseed oil but this was not statistically significant.

1st degree excoriation was found in patients having surgery because of enteric perforation while 2nd degree excoriation was found in patients of necrotizing enterocolitis and intussusception irrespective of the agent used for prevention of excoriation.

It's common knowledge that zinc can support the health of your immune system. Immune-boosting potential of zinc is one of the reasons why it should be used in Peristomal dermatitis when the skin is suboptimal and there are chances of infection. Zinc not only strengthens the response of the immune system to skin irritation but also speeds

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up the process by which new skin cells proliferate to replace damaged ones.

Many studies used zinc oxide as standard in prevention and management of Peristomal dermatitis and excoriation. Arad et al. published a study in which he compared the eosin with zinc oxide labelling as standard for management of stool related dermatitis [7]. In study conducted by Wananukul et al. dexpanthenol was compared with zinc oxide ointment taking it as standard against diarrhea associated dermatitis and excoriation [8]. In another study conducted by Ramirez Razor for incontinence-associated dermatitis (IAD), treatment with two zinc oxide-based ointment was compared to seeing the efficacy while taking zinc oxide as standard [9].

Very limited data is available on abilities of linseed oil in prevention of Peristomal dermatitis and excoriation. A study conducted by Saxena in 2014 on efficacy of linseed oil in management of Peristomal excoriation showed that only 17 percent of patients with stoma had grade 1 Peristomal excoriation while the rest did not have any excoriation [10].

In our study, zinc oxide is taken as standard against which linseed oil treatment was compared, and results were found to be comparable with respect to excoriation prevention showing linseed oil can be used as an alternative for prevention and management of Peristomal dermatitis and excoriation.

Flax seed oil, also known as linseed oil or flax seed, is made from the dried, ripe seeds of the linaceae family plant known by the name of Linum ustitatissimum in botany (also known as Alsi in hindi). The oil is white to yellowish. It is rich in Alpha linoleic acid (ALA) which is an omega-3 polyunsaturated fatty acid. About 30–40% of seeds are fixed oil, 25% are proteins, 6% are mucilage, and there are also trace amounts of wax, resin, sugar, phosphate, and glucosides and linamarin [5].

One of the sources of plant based ω3-α linolenic acid is linseed oil, which also contains a significant amount of vitamin E, ω9 and ω6 fatty acids, as well as a variety of phytonutrients [11]. Furthermore, the hydrophobic coating formed by the oil based nature of linseed oil keeps the ileostomy effluence's enzymes from getting into touch with the skin. Due to its high unsaturated ester content, linseed oil is especially vulnerable to polymerization processes when exposed to airborne oxygen. This might lead to hardening or dry film formation, which further protects the skin from the enzymes in the ileostomy output [12]. The presence of lignans in linseed oil may help protect the skin from skin cancer as well as breast, colon, and prostate cancer [11]. After a thorough online and library search, there is a dearth of information regarding the benefits of linseed oil in the prevention of skin dermatitis/excoriation; thus, a reasonable explanation for its use is discussed. Because linseed oil's oily base soothes peri-stomal skin and reduces dermal damage from iliostomy contents spilling, there is very little to no excoriation while using it. Without halting cellular irespiration, the oil-based linseed oil creates a protective barrier that shields the peri-stomal skin from skin irritants originating from the stoma [10].

In addition to the aforementioned benefits, linseed oil is more widely available, extremely affordable, and simple to use than other ointments. Once more, linseed oil administration reduced skin excoriation in individuals with hemoglobin levels below average (<8 gm %), in whom we expect poor wound healing. It is wise to use agents like linseed oil, whose efficiency is largely unaffected by hemoglobin status and nutritional status, as we have seen, since usual patients in our country have mean hemoglobin less than 10gm% due to dietary abnormalities and malnutrition and in patients with ileostomies nutritional status further deteriorates.

When it comes to treating different wounds, using locally sourced and traditionally utilized materials like betel leaf [14] and honey [13], linseed oil is more cost-effective and is more well-liked by patients who are less well-off.

Conclusion:

Peristomal excoriation and dermatitis is a common issue in patients after stoma formation. It decreases the quality of life and health of a patient. Agents should be used to prevent Peristomal complications. Linseed oil is a cheap agent which is easily available and is near to

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standard care in preventing Peristomal excoriation. Study on larger scale should be conducted to see its application in general population having Peristomal and perianal dermatitis.

Conflict of Interest: There is no conflict of interest

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