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Topical Steroid Versus Emollient For Prevention of Radiodermatitis in Head and Neck Carcinoma, A Comparative study.

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Abstract

Background:-

Head and neck cancer (HNC) is the seventh most common cancer globally; accounting for more than 660,000 new cases and 325,000 deaths annually .There appears to be an increasing incidence of this disease, with potential changes in etiology proposed given the decline of smoking, particularly in developed countries. There are various methods of treatment for head and neck carcinoma i:e surgery ,radiation and chemotherapy . Definitive chemoradiotherapy (CRT) is widely used under a variety of conditions in locally advanced Squamous cell carcinoma of the head and neck (LA-SCCHN). A common acute toxicity in CRT is radiation dermatitis. This is often more severe than that in radiotherapy alone. Various treatments are used in radiation dermatitis for example washing with saline, application of local steroid and emollients .In this study ,we evaluated the effect of potent topical steroid(Mometasone Furoate cream vs emollient) on acute radiation dermatitis in head and neck cancer patients receiving curative radiotherapy.

Methods:-A total 90 patients of head and neck cancers were randomly divided into arm A 45 patients(emollient) and arm B 45 patient (steroid). The patients in arm A were treated with emollient and the patients in study arm B were treated with topical Mometasone Furoate twice daily during radiotherapy/ chemo-radiotherapy. The radiation reaction in both the groups was monitored weekly according to Radiation Therapy Oncology Group (RTOG) acute radiation dermatitis grading.

Results:- Grade 1 skin reaction was seen in 2.22% in group A in week 1 while as no reaction was seen in group B .In second week 40% had grade 1 and 15.55% had grade 2 reactions in group A while as in Group B grade 1 reaction was seen in 22.22% and 2.22% had grade 2 skin reaction . In 3 rd week 2.22% had grade 1 skin reaction , 6.66% had grade 2 and 4.44% had grade 3 skin reaction in Group A while in Group B there was increase in grade 1 skin reaction (31.11%)and grade 2 reactions(17.77%).

With4th, 5thand 6thweek grade 1 reaction was higher in Group A than group B and grade 2 and grade 3 reaction also remained higher in Group A. By the end of the 7th week, Grade 1 was reaction was seen in one patient in Group A and while no reaction was seen in Group B .Grade 1 reaction was significantly higher in group A than Group B, (P value 0.828), grade 2 was also higher in Group A vs Group B(P value -0.546)while no grade 3 was seen in group B(P value- 0.199).

No difference was seen in subjective symptoms of these two groups. Treatment break due to radiation toxicity was 51.11% in emollient group A and while In group B it was 28.88% .All the 90 patients who took radiation were advised about importance of post treatment follow up and 60(66.66%) patients came for follow

up . 30 patients in each arm were evaluated for healing and skin changes. 83.0% (25/30) of patients in Group B had healing of skin within 8 days while 50%(15/30) of patients in Group A took more than 12 days to heal.
Conclusions: - We conclude that Mometasone cream can delay the progression of radiation dermatitis in head and neck cancer and can prevent grade 3 and 4 reactions if initiated early. It can be used for longer duration that is more than seven weeks with minimal side effects.

Keywords: Emollient, Radiation dermatitis, Squamous cell carcinoma, Steroids

Introduction

Head and neck cancer (HNC) is the seventh most common cancer globally, accounting for more than 660,000 new cases and 325,000 deaths annually[1,2]. There appears to be an increasing incidence of this disease, with potential changes in etiology proposed given the decline of smoking, particularly in developed countries.

According to the GLOBOCAN 2020, head and neck cancers are the second most common cancer in India among both sexes and all ages with 135,929 (10.3%) of new cases and ranks third for death toll with 75,290 (8.8%) cases. The 5-year prevalence for all ages is 21.77 per 100,000 [1].

The primary risk factors associated with head and neck cancer include tobacco use, alcohol consumption, human papilloma virus (HPV) infection (for oropharyngeal cancer), and Epstein-Barr virus (EBV) infection (for nasopharyngeal cancer). The chronic exposure of the upper aero digestive tract to these carcinogenic factors can result in dysplastic or premalignant lesions in the oropharyngeal mucosa and ultimately result in head and neck cancer. The relative prevalence of these risk factors contributes to the variations in the observed distribution of head and neck cancer in different areas of the world[3].

There are various methods of treatment for head and neck carcinoma, surgery, chemotherapy and radiation Definitive chemo radiotherapy (CRT) is widely used under a variety of conditions in locally advanced Squamous cell carcinoma of the head and neck (LA-SCCHN) [1–5]. The standard chemo radiotherapy regimen for LA-SCCHN is single agent Cisplatin and concurrent radiotherapy (definitive setting; Cisplatin 100 mg/m2 q3weekly or Cisplatin 40mg/m2 weekly RT 70Gy/35fractions, postoperative setting Cisplatin 100 mg/m2 q3weekly or Cisplatin 40mg/m2 weekly RT 60-66Gy/30-33fractions). A common acute toxicity in chemo radiotherapy and radiation is radiation dermatitis. This is often more severe in CCRT than in radiotherapy alone.[4-8].

Radiation dermatitis often leads to treatment interruption during long duration of radiotherapy, such as in head and neck cancer [9]. Furthermore, the combination of radiotherapy and chemotherapy increases skin reactions, resulting in severe xerosis, inflammation, skin thinning, and necrosis of the upper dermis and epidermis [10].

Radiation dermatitis is the result of underlying inflammatory process, due to release of cytokines like TNFα, IL-6, IL-1[11-13] after radiation exposure. Beetz et al. reported an up-regulation of IL-6 expression in an irradiated human epithelial cell line, which could be inhibited by corticosteroids [13]. Corticosteroids produce an anti-inflammatory effect by down regulation of cytokine gene expression, inhibition of adhesion, and migration of inflammatory cells, which can be postulated as ideal for management of radiation dermatitis [14-15].But exact mechanism of this anti- inflammatory effect of corticosteroid on radiation dermatitis is not yet completely understood

Although various treatments are used in radiation dermatitis for example washing with saline, application of local steroid and emollients. But still, there is no guideline or even uniform consensus among radiation oncologists regarding management of radiation dermatitis. Topical application of anti-inflammatory drugs such as corticosteroids, aloeveragel, honey, and homeopathic remedies is the most common treatment for acute radiation dermatitis.[16,17].However, the results are not always satisfactory. Recently, some studies showed that local application of Mometasone Furoate cream

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(MMF) significantly reduced acute radiation dermatitis[18, 19].Mometasone Furoate cream (MMF) is a synthetic corticosteroid and has 3 potential advantages over other topical corticosteroids. First, it is a potent corticosteroid with a low risk of overt cutaneous atrophy [20]. Second, the local application has been claimed to have a prolonged effect, lasting for 24hours, and thus requires only once-a-day application third, it has been confirmed that Mometasone Furoate cream has a strong inhibitory effect on IL-6 activity, both on the transcriptional and protein levels, during radiotherapy [21]. Various studies have been done evaluating the use of topical steroid in preventing radiation dermatitis. In this study we have also evaluated the effect of topical steroid Mometasone Furoate cream and compared it with emollient.

Methods: -This study was conducted at Government Medical College, Srinagar. A total of 150 patients attended our clinic from March 2022 to August 2022 of which 90 patients were included in the study.

All patients who presented with histopathologically proven primary Squamous cell carcinoma of head and neck, with or without lymph node metastasis, who were planned for definitive radiotherapy or chemo-radiotherapy with curative intent, were included.

Exclusion criteria were cutaneous diseases, allergy to any topical steroid, uncontrolled Co –morbidities, previous radiation in head and neck region, para nasal sinus and salivary gland tumor. An informed consent was taken from all patients.

We randomized patients in 1:1 ratio in two arms, as per sequence of their enrolment in the trial. Neither the patient nor the reviewer was blinded. The 45 patients in study arm A received emollient over the radiation area from day one, while 45 patients in arm B were instructed to use steroid (Mometasone Furoate) from day one. All patients were advised to wash face and neck with clean normal water.

All patients received external beam radiation therapy in the dose of 66gy -70gy depending on the stage and chemotherapy weekly. Cisplatin was administered in some and while radiation alone was given in some patients depending on the primary site and stage. All techniques including Volumetric Modulated Arc Therapy (VMAT), 3-Dimensional Conformal Radiotherapy (3DCRT), conventional and Intensity Modulated Radiation Therapy (IMRT) were included in this study. The contouring in case of conformal techniques was done based on Danish Head and Neck Cancer (DAHANCA) guidelines.

The chemotherapy was given in form of Cisplatin 40mg/m2 weekly.

Application:-

The patients in Group A and Group B were instructed regarding the proper application over the radiation area before starting radiation. Mometasone Furoate cream and emollient has to be started preferably from first day and not later than third day of radiation. Before every application, patients were instructed to wash face and neck with normal plain water and let it dry, after which a thin layer of cream in one fingertip unit had to be applied on each side of face and neck up to the clavicle. The application was done twice daily, first in the morning before taking radiotherapy and then in the evening after taking radiotherapy. Emphasis was given regarding the maintenance of proper hygiene and not to wear closed tight collar dress to avoid skin infection and mechanical irritation. Patients were evaluated after every five fractions of radiation and compliance to emollient use was noted in arm A and steroid use in Arm B and skin care was noted in both the arms. Symptomatic treatment was given for itching.

The adverse reaction in the skin was visually described and recorded according to Radiation Therapy Oncology Group(RTOG) acute radiation morbidity scoring criteria.Radiotherapy was interrupted in patients who developed grade 3 skin reactions characterized by confluent moist desquamation. The wound dressing with normal saline was done daily under sterile conditions and antibiotics given when necessary. Once healed, remaining radiation dose was completed as planned and patients were not excluded from study.

The severity of radiation dermatitis, presence or absence of infection in the irradiation field, performance status, dietary intake, and other toxicities were evaluated at least weekly from the initiation of Concurrent chemo radiation and radiation to 1 month after the end of it.

Statistical Analysis: -Analysis of data was done using IBM SPSS software version 22. Pearson Chi

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square test was used to compare the characteristics and results between the two arms.

Results: - A total of 150 patients attended our clinic from March 2022 to August 2022 of which 90 patients were randomly included in the study. Group A was given emollient for application and Group B was given steroid for application. Baseline patient characteristics with respect to demographic are given in Table 1.

Concurrent chemo radiation was given in 24 patients (53.33%) in both definitive settings and adjuvant settings while as radiation only was given in 21(46.66%) patients depending on stage in group A while as in Group B 27(60%) patients received Concurrent chemo radiation in both definitive and adjuvant settings and 18(40%) patients received radiation only(Table2). 22.22% patients in group A had history of skin incision in the irradiatiation field while as 20% in group B had history of skin incision in irradiation field.(Table 2).

More than 90% of the patients completed the treatment protocol in both groups. Patients were followed for adherence to radiation.

Grade 1 skin reaction was seen in 2.22% in group A in week 1 while as no reaction was seen in group B (Table 3).In second week 40% had grade 1 and 15.55% had grade 2 reactions in group A while as in Group B grade 1 reaction was 22.22% and 2.22% had grade 2 skin reactions (Table 3). In 3 rd week 2.22% had grade 1 skin reaction , 6.66% had grade 2 and 4.44% had grade 3 skin reaction in Group A while in Group B there was increase in grade 1 skin reaction (31.11%)(Graph 1) and grade 2 reactions(17.77%) (Table3).

With 4th,5thand 6thweek grade 1 reaction was higher in Group A than group B (Graph 1) and grade 2 (Graph2) and grade 3 reaction also remained higher in Group A(Graph3).By the end of the7th week, Grade 1 reaction was seen in one patient in Group A and while no reaction was seen in Group B(Graph 1) Grade 1 reaction was significantly higher in group A than Group B,(P value 0.828) , grade 2 was also higher in Group A vs Group B(P value -0.546)while no grade 3 was seen in Group B(P value- 0.199).

No difference was seen in subjective symptoms of these two groups. Treatment break due to radiation toxicity was 51.11% in emollient group A and while In Group B it was 28.88% (Table 2). All the 90 patients who took radiation were advised about importance of post treatment follow up and 60(66.66%) patients came for follow up. 30 patients in each arm were evaluated for healing and skin changes. 83.0% (25/30) of patients in Group B had healing of skin within 8 days while 50%(15/30) of patients in Group A took more than 12 days to heal.

Discussion:-Radiation-induced dermatitis is a very common side effect of radiotherapy and may necessitate the stoppage of therapy, at times creating problem not only for the patient but also for the radiotherapist viz studies conducted by Bostrim et al [19] and Dini et al [22]. A wide variety of pharmacological and non pharmacological therapies have been suggested for radiation dermatitis from time to time viz Dini et al [22].

The topical steroid has delayed the onset and progression of radiation dermatitis as well as improved quality of life in breast cancer patients receiving radiation viz Farhan et al[23]. Some studies did not show any benefit over placebo or moisturizing cream, but in these studies either steroid of mild potency was used or application was started after onset of dermatitis[24, 25,26] When potent steroid like Betamethasone or Mometasone Furoate was compared with moisturizing cream or emollient, benefit of steroid was significantly evident viz Ulfee et al[27] which is similar to our studies where the benefit of steroid is significantly better.

In spite of good results shown in carcinoma breast fewer trails have been done in use of topical steroids in head and neck carcinoma. In this study we have used topical Mometasone Furoate and compared it with emollient. In this study we found that Mometasone Furoate cream delayed the onset of grade 1 dermatitis and it should be started prophylactically along with radiation which is similar to study conducted by Sunku et al [28]. We also found that severity of grade 2 reaction was less in steroid group as compared to emollient which is similar to a study conducted by Yokota et al[29].We also found that grade 3 radiation dermatitis was not found in steroid which suggest that it is therapeutically useful in reducing severity which is similar to study conducted by Shukla et al[30].Time taken for skin healing was almost same as in emollient group. No skin changes such as eczema and

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atopic dermatitis was seen in steroid group which came up for follow up.

Limitations:-

Evaluation of skin reaction was done by visual inspection which could slightly vary between observers. Longer duration of follow up is needed for documentation of systemic side effects.

Conclusion: -We conclude that Mometasone cream can delay the progression of radiation dermatitis in head and neck cancer and can prevent grade 3 and 4 reactions if initiated early. It can be used for longer duration that is more than seven weeks with minimal side effects.

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Table 1: Comparison of patient's characteristics between Group A and Group B

	Group A	Group B		
	{ Emollient (% within group)}	{ Steroid MMF (% within group)}	Total	P
Age				
<45 yrs	7 (15.5)	8(17.77)	15(16.6)	1
45-60 yrs	28 (62.2)	22 (48.88)	50(55.54)	
>60 yrs	10 (22.22)	15 (33.33)	25(27.77)	
Gender				
Male	37 (82.22)	38 (84.44)	75(83.33)	1
Female	8 (17.77)	7 (15.55)	15(16.66)	
ECOG				
0	11 (24.44)	10 (22.22)	21(23.33)	1
1	31 (68.88)	24 (53.33)	55(61.10)	
2	3 (6.66)	11 (24.44)	14(15.55)	
3	0 (0)	0 (0)	0(0)	
4	0 (0)	0 (0)	0(0)	
Co morbidity				
Yes	21 (46.66)	20 (44.44)	41(45.55)	1
No	24 (53.33)	25 (55.55)	49(54.44)	
Education				
Literate	41 (91.11)	38 (84.44)	79(87.77)	1
Illiterate	4 (8.88)	7 (15.55)	11(12.21)	
Smoking				
Yes	27 (60)	31 (68.88)	58(64.44)	1
No	18 (40)	14 (31.11)	32(35.55)	
Alcohol				
Yes	0 (0)	1 (2.22)	1(1.11)	1
N0	45 (100)	44 (97.77)	89(98.98)	
Primary site				

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Nasopharynx	10 (22.22)	9 (20)	19(21.11)	0.91
Oropharynx	0 (0)	1 (2.22)	1(1.11)	
Hypopharynx	0 (0)	0 (0)	0(0)	
Larynx	21 (46.66)	27 (60)	48(53.33)	
Oral cavity	14 (31.11)	8 (17.77)	22(24.44)	
Settings				
Adjuvant	9 (20)	10 (22.22)	19(21.11)	1
Definitive	36 (80)	35 (77.77)	71(78.8)	
Incision in Radiation field				
Yes	10 (22.22)	9 (20)	19(21.1)	1
No	35 (77.77)	36 (80)	71(78.8)	
Radiation Technique				
3DCRT	0 (0)	1 (2.22)	1(1.11)	1
IMRT	1 (2.22)	3 (6.66)	4(4.44)	
VMAT	30 (66.66)	22 (48.88)	52(57.77)	
Conventional	14 (31.11)	19 (42.22)	33(36.66)	

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Table 2: Comparison of treatment characteristics between Group A and Group B

	Group A (% within group)	Group B (% within group)	Total (%)	p
Radiotherapy Dose received (in Gy)				
1-19	0 (0)	0 (0)	0(0)	1
20-65	2 (4.44)	5 (11.11)	7(7.77)	
66-70	43 (95.55)	40 (88.88)	83(92.2)	
Gap during Treatment				
Yes	23 (51.11)	13 (28.88)	36(39.9)	1
No	22 (48.88)	32 (71.11)	54(59.9)	
Duration of Ointment application				
1-5 weeks	1 (2.22)	2 (4.44)	3(3.33)	1
6-7 weeks	12 (26.66)	34 (75.55)	46(51.1)	
7-9 weeks	32 (71.11)	9 (20)	41(45.55)	
Chemotherapy				
Weekly	24 (53.33)	27 (60)	51(56.6)	1
Tri-weekly	0 (0)	0 (0)	0(0)	
No chemo	21 (46.6)	18 (40)	39(40)	

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Table 3: Comparison between radiation dermatitis between Group A and Group B at 1st week to 7th week

Week	Group	Grade 0	Grade1	Grade2	Grade 3	Grade 4	Missing	p
1	A	44 (97.77)	1 (2.22)	0 (0)	0 (0)	0 (0)	0 (0)	1
	B	45 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
2	A	20 (44.44)	18 (40)	7 (15.55)	0 (0)	0 (0)	0 (0)	1
	B	34 (75.55)	10 (22.22)	1 (2.22)	0 (0)	0 (0)	0 (0)	
3	A	39 (86.66)	1 (2.22)	3 (6.66)	2 (4.44)	0 (0)	0 (0)	1
	B	23 (51.11)	14 (31.11)	8 (17.77)	0 (0)	0 (0)	0 (0)	
4	A	31 (68)	7 (15.55)	7 (15.55)	0 (0)	0 (0)	0 (0)	1
	B	41 (91.11)	2 (4.44)	2 (4.44)	0 (0)	0 (0)	0 (0)	
5	A	40 (88.8)	2 (4.44)	2 (4.44)	1 (2.22)	0 (0)	0 (0)	1
	B	43 (95.5)	1 (2.22)	1 (2.22)	0 (0)	0 (0)	0 (0)	
6	A	43 (95.5)	2 (4.44)	0 (0)	0 (0)	0 (0)	0 (0)	0.16
	B	0 (0)	0 (0)	0 (0)	0(0)	0 (0)	0 (0)	
7	A	44 (97.7)	1 (2.22)	0 (0)	0 (0)	0 (0)	0 (0)	0.35
	B	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	

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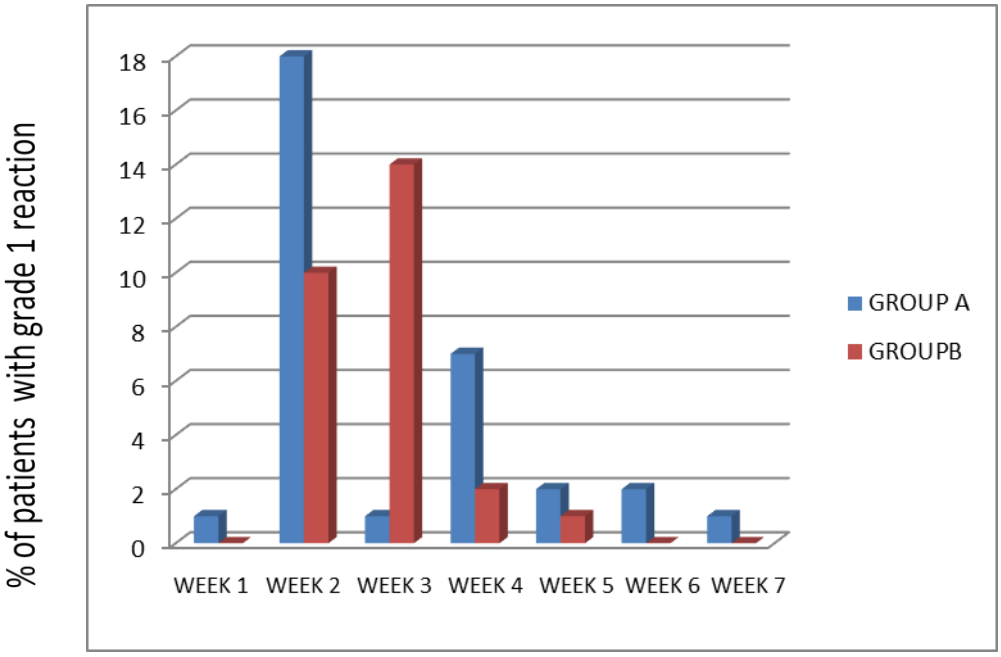
Graph 1: Percentage of grade 1 reaction from week 1 to week 7



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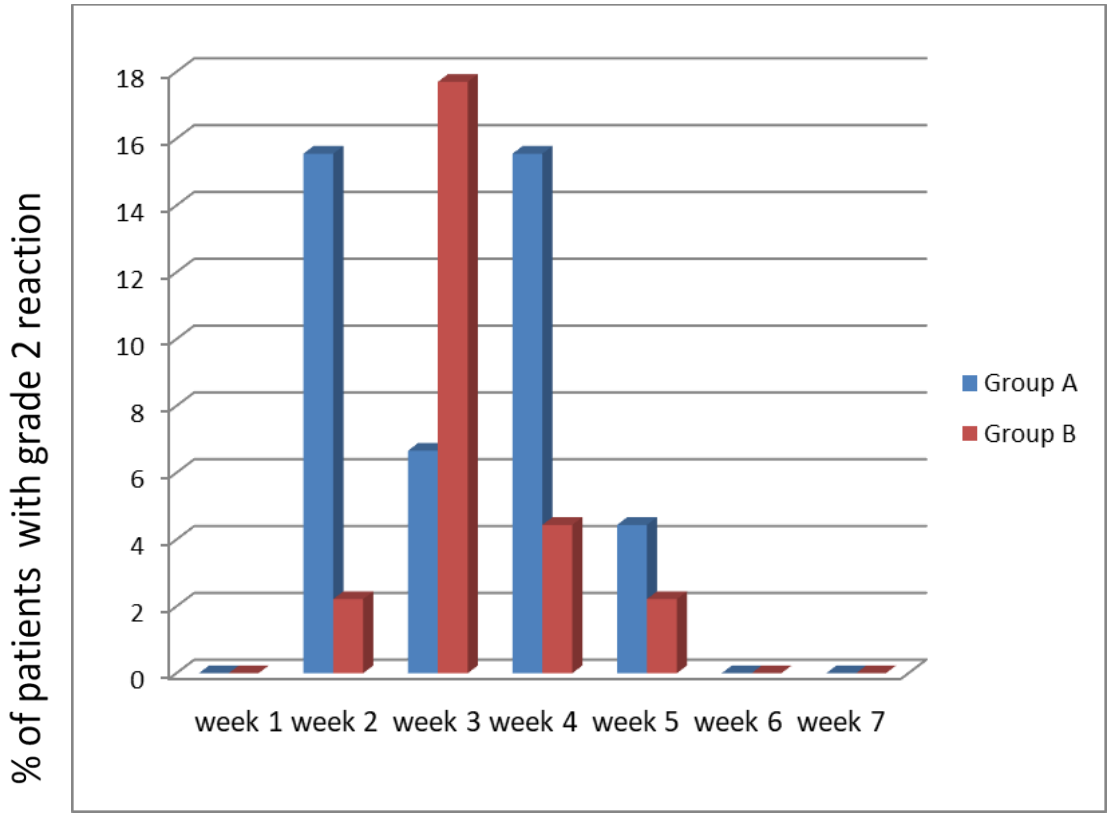
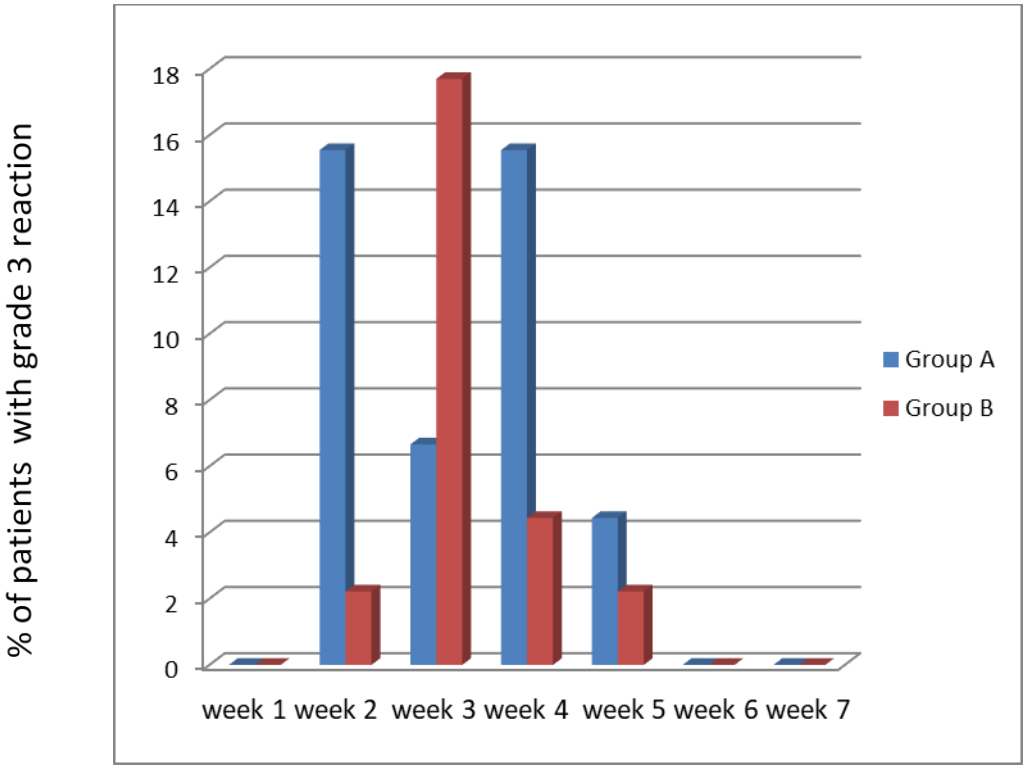
Graph 2: Percentage of grade 2 reaction from week 1 to week 7



Graph 3: Percentage of grade 3 reaction from week 1 to week 7



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