

Research Note

Rhinocort vs Eltair: A comparative review of a patented and generic drug

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Abstract. Rhinocort and Eltair are both the patented and generic equivalent of the topical nasal steroid budesonide. A study consisting of 42 patients was conducted at the ENT department of Hospital Ipoh to compare the response of patients who were using Rhinocort prior to Eltair. The results show statistically significant symptomatic response and lower complications with Rhinocort compared to Eltair.

Rhinocort and Eltair are both topical nasal steroids in which the active compound is budesonide. Rhinocort is the trade name for the original patented drug, which has been in the market for more than 20 years. Eltair is a recent generic alternative. It was introduced to Hospital Ipoh in the year 2000 to replace Rhinocort due to cost factors.

Rhinocort is widely used in the treatment of allergic rhinitis. With the introduction of Eltair many patients were switched to this cheaper alternative. However, numerous complaints arose. The department of E.N.T. Hospital Ipoh then decided to undertake a study to determine the nature and extent of the grievances.

The study was a prospective study. The patients included in the study were previously on Rhinocort and subsequently switched to Eltair. All patients fulfilling the above criteria were selected during four consecutive clinic-sittings. Questionnaires were given to the patients and the results were documented and tabulated. A total of 42 patients were included in this study.

In the first part of the study the symptomatic response of the patients to

both the drugs was evaluated; general as well as specific symptoms such as sneezing, nose-block and nasal discharge. A grading of 1, 2 and 3 was given to each one of these indices depending on the level of response i.e. improved/reduced, same or worse. The grading of each of these indices was added up giving to a minimum total score of 4 and a maximum of 12. The lower the score the better the symptomatic response obtained by the patient.

The second part of the study looked into comments by the patients regarding the usage and side-effects produced by the drugs. The factors looked into were pain, irritation, delivery system, taste and compliance.

The sample consisted of 42 patients of whom 23(55%) were females and 19(45%) males. 41 patients(98%) found the general response using Rhinocort good, while 1 patient found it fair and none, poor. With Eltair 2(4.7%) patients found the general response good, 19 patients(45%) had a fair response while 21(50%) responded poorly to it. After switching to Eltair most patients found their symptoms to be the same. Sneezing-33(79%), nose block-

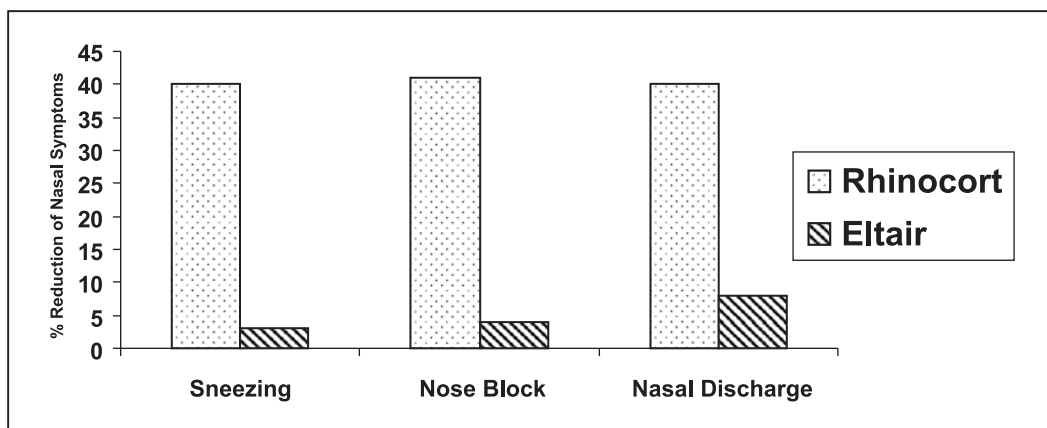


Figure 1. Bar-Chart showing reduction of nasal systems comparing Rhinocort with Eltair.

28(66%) and nasal discharge-24(57%).Some even found their symptoms to be getting worse.

Specific symptoms such as sneezing, nose block and nasal discharge showed significant improvement with Rhinocort (Fig. 1) based on a chi-squared test for each symptom; $p < 0.01$ (95% confidence interval).

More than half the patients, 28, found Eltair to be painful compared to 4 with Rhinocort. Twenty-two patients (52%) complained that Eltair caused nasal irritation. None complained of the Rhinocort delivery system. An equal number found the delivery system of Eltair to be bad as it frequently got stuck in the nostrils. Few, 5(12%) complained about the taste of Rhinocort while 28(67%) disagreed with the taste of Eltair; leaving a bitter taste in many of the patients. Twenty-nine patients (69%) were found to be non-compliant to Eltair. Rhinocort showed a good compliance of 95% or 40 patients from the study. The difference in pain, irritation and compliance was significant, $p < 0.01$ (chi-squared test, 95% confidence interval). (Fig. 2)

Escalating medical costs have resulted in generic substitution for brand-name drugs becoming increasingly common. In third world countries particularly generic drugs have contributed greatly in the provision of quality and cost effective health care. However, barring economic

Table 1. Symptomatic patient response; rhinocort vs. Eltair

		Rhinocort	score	Eltair	score
Response	1. good	41	41	2	2
	2. fair	1	2	19	38
	3. poor	0	0	21	63
Sneezing	1. improved	40	40	3	3
	2. same	2	4	33	66
	3. worse	0	0	6	18
Nose block	1. reduced	41	41	4	4
	2. same	1	2	28	56
	3. worse	0	0	10	30
Nasal discharge	1. reduced	40	40	8	8
	2. same	2	4	24	48
	3. worse	0	0	10	30
Total			175		353

Table 2. Usage And Side-effects

		Rhinocort	Eltair
Pain	Yes	4	28
	No	38	14
Irritation	Yes	5	24
	No	37	18
Delivery system	Good	42	20
	Bad	0	22
Taste	Good	37	14
	Bad	5	28
Compliance	Good	40	13
	Bad	2	29

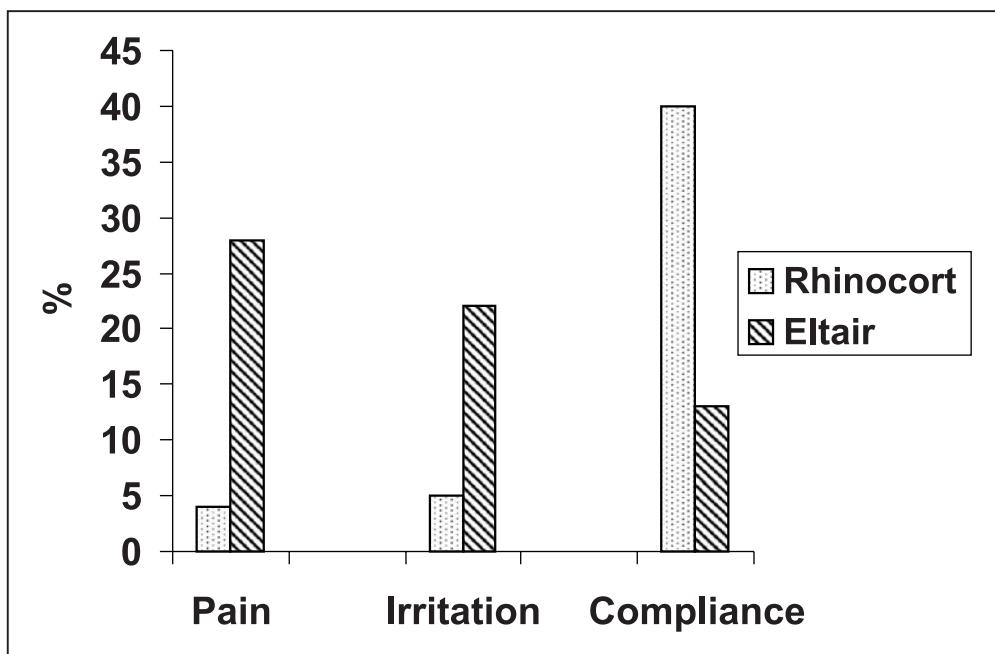


Figure 2. Bar-Chart Showing Side-Effects and Compliance Rhinocort vs Eltair.

concerns, before a decision is made to introduce a generic product, other factors have to be taken into account such as the efficacy and safety of the generic equivalent.

Problems have been encountered with generic substitution. In the United States the F.D.A. recalled a generic version of the antirejection drug cyclosporin, oral solution, because of clinical evidence that the generic drug's availability was low when administered with apple-juice. (Henney, 2000)

Fiscella *et al.* (1998) encountered problems with the usage of generic 1% prednisolone acetate ophthalmic suspension. The generic was found to go into suspension with difficulty, requiring at least 70 shakes before a homogenous suspension was obtained. Another generic equivalent product developed a clogged dropper tip, with what appeared to be precipitated prednisolone acetate.

Continuity of supply was an issue raised by Skinner (2000), an anesthetist in the United Kingdom. He found that critical drugs particularly suxamethonium were in short supply threatening to disrupt

emergency and elective surgeries. He advocated that manufacturers of these drugs should be rewarded not only for the work of making them but also for the reliability of supply for certain drugs.

To our knowledge there are no other published studies on generic Budesonide. In this study the majority of the patients found Rhinocort to be more effective in giving greater symptomatic relief. The generic, Eltair was found to have unpleasant side-effects such as pain, irritation and bad taste resulting in poor compliance.

Despite its benefit in reducing costs, there are problems with generic substitution. In the United States the F.D.A. requires that all drug products met specifications for identity, strength, quality, purity and potency. Bioequivalence studies are carried out and additional clinical or laboratory assessment may be required before a drug is approved. (Henney, 1999; Nightingale, 1998)

Adequate measures, similar to the FDA in the United States should be taken by the relevant authorities to carefully vet generic substitutions before approval for public

usage. Costs alone should not be the criteria to introduce a generic; whatever drug given to a patient should ultimately achieve its therapeutic aim.

* Eltair was finally discontinued in Hospital Ipoh after the numerous complaints and complications documented with its usage.

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