

Irritant Skin Reactions to Urostomal Adhesives

B. Bergman*, G.-B. Löwhagen and H. Mobacken

Department of Urology, University of Umeå, and Department of Dermatology, University of Göteborg, Sweden

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Summary. The skin irritation evoked by urostomal adhesives with three different types of adhesive material was investigated. The 74 test subjects had previously not been using stomal appliances. A standard patch test was performed on normal skin of the back for 48 h, and readings were made 1 and 24 h later. The lowest irritation was observed after an adhesive disk composed of pectin, gelatine and sodium carboxymethylcellulose.

Key words: Urinary diversion, Ileal conduit, Irritant dermatitis, Patch testing, Urostoma.

Introduction

Irritant Skin Reactions to Urostomal Adhesives

A transient or persistent dermatitis around a urostoma is not uncommon [1, 4]. Such reactions not only cause discomfort but can become a major medical and nursing problem. Irritant reactions are considered to be more prevalent than contact allergies [9]. There are probably many factors which contribute to the dermatitic response: individual predisposition [6], varying irritant potential of the adhesive, leakage of urine, length of the protruding intestinal "nipple", use of irritant solvents and disinfectants, traumatising of the skin upon removal of appliance etc. [1]. The multifactorial aetiology is exemplified by the chronic irritant dermatitis we recently reported with the clinical appearance of papillomatous peristomal lesions [1]. This gave us the impetus to analyse one of the provocative factors, the irritant capacity of the adhesive disc of the urine-collecting appliance. The aim of this study was to assess if a difference in the irritant potential of different sorts of adhesives could be demonstrated by a 2 day exposure of normal human skin.

Material and Methods

Skin tests were performed in 74 patients, 51 males and 23 females. The mean age was 66 years (range 20–86). They were all hospitalised for various skin diseases or were awaiting cystectomy for carcinoma of the urinary bladder. Patients with eczematous reactions were not included. All had normal skin on the back. None were on systemic corticosteroid or immunosuppressive therapy. The test was performed using stomal adhesives of the three different types available; i.e. with the glue based upon rubber, polyacrylate or a mixture of pectin, gelatine and sodium carboxymethylcellulose. The seven investigated adhesives and their manufacturers are listed in Table 1.

The adhesive plates were cut into pieces 5 × 5 cm by a laboratory technician, and applied to the back of the patients in a vertical row. The location of the adhesive in the row was determined using a random table. All tests were done in duplicate with another vertical row of adhesives symmetrically on the other side of the spine after a new randomisation. The test samples were removed after 48 h. Adhesives which had fallen off were registered. Readings were made at 1 and at 24 h after removal of the adhesive by a dermatologist who was unaware of the location of the different adhesives. The patients were not allowed to bath or have a shower during the test. The skin reactions were graded from 0 to 3 as follows:

- 0 = no skin reaction
- 0.5 = doubtful erythema
- 1.0 = just perceptible erythema
- 1.5 = erythema with doubtful infiltration
- 2.0 = erythema with clear infiltration
- 2.5 = erythema with infiltration and < 3 papules and/or vesicles
- 3.0 = erythema with infiltration and > 3 papules and/or vesicles

Statistical Methods

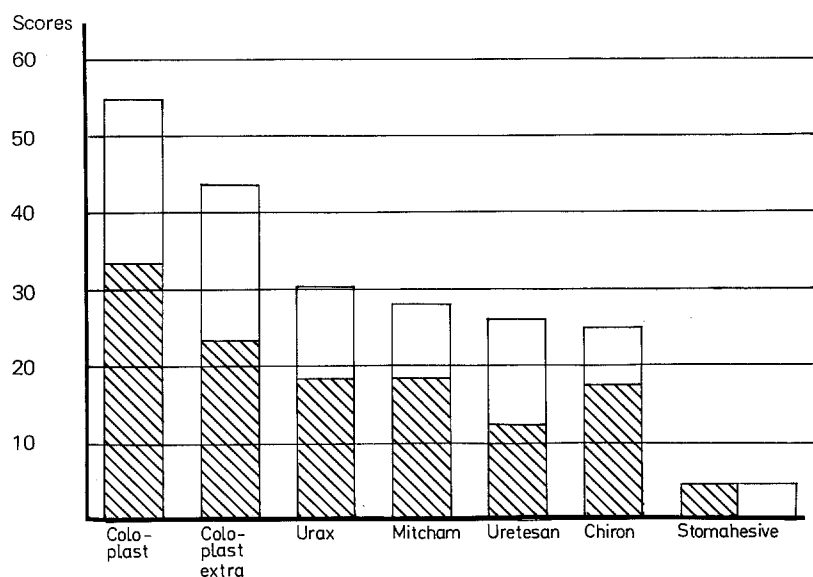
Each adhesive was compared to the others using Fisher's permutation test for pair differences [2, 10], which is a non-parametric test. When comparing two adhesives the difference in skin reaction score was calculated for each patient. The *p*-value equals the conditional probability that the sum of differences is at least as extreme as the sum obtained given that the absolute values of the differences equals the observed ones. The Fisher test has advantages compared to other tests. Contrary to the Wilcoxon test for pair differences, the information of the original data is used to the same extent as when applying the *t*-test for pair differences.

A special technique of approximation (the Edgeworth expansion and Sheppard's correction) was applied at the calculation of the *p*-values [3, 11].

* Address correspondence to: Dr. Bo Bergman, Department of Urology, University of Umeå, S-901 85 Umeå, Sweden

Table 1. Results from patch tests on normal skin for 48 h with different adhesives. Readings were made 1 and 24 h after removal

Type of adhesive Trade name ^a	Material ^b	Number patients		Number pos. tests (%)		Mean \pm sem of pos. and neg. tests		Mean \pm sem of pos. tests	
		1 h	24 h	1 h	24 h	1 h	24 h	1 h	24 h
Chiron (Stille-Werner [Down], Stockholm)	Ru	72	64	26	18	0.17 \pm 0.03	0.14 \pm 0.04	0.66 \pm 0.07	0.76 \pm 0.14
Coloplast (Beiersdorf AB, Kungsbacka)	Ru	72	64	41	19	0.39 \pm 0.06	0.27 \pm 0.06	0.92 \pm 0.04	1.40 \pm 0.19
Coloplast extra (Beierdorf AB, Kungsbacka)	Ru	72	64	40	20	0.33 \pm 0.05	0.21 \pm 0.05	1.14 \pm 0.43	0.90 \pm 0.17
Urax (Duni-Bilå AB, Halmstad)	Ru	72	64	28	19	0.21 \pm 0.04	0.14 \pm 0.04	0.61 \pm 0.07	0.73 \pm 0.15
Uretesan (AB Hedima Medical, Malmö)	Pa	72	64	31	14	0.18 \pm 0.02	0.10 \pm 0.03	0.56 \pm 0.03	0.69 \pm 0.10
Mitcham (Stille-Werner [Down], Stockholm)	Ru	72	64	31	18	0.20 \pm 0.03	0.15 \pm 0.04	0.63 \pm 0.05	0.72 \pm 0.13
Stomahesive (Squibb, Lidingö)	PG	72	63	6	7	0.03 \pm 0.01	0.04 \pm 0.01	0.50	0.50

^a Names of manufactures within brackets^b Ru = Rubber; Pa = Polyacrylate; PG = Pectin, gelatin and sodiumcarboxymethylcellulose**Fig. 1.** Total test scores for individual adhesives. Readings were made 1 h (▨) and 24 h (□) after removal of the adhesives

Results

Of the 74 patients tested two were not read after 1 h and 10 were not read after 24 h. Plasters that had fallen off spontaneously were one piece for Chiron, two for Coloplast, five for Coloplast extra, six for Mitcham and none for Urax, Uretesan and Stomahesive. The degree of skin irritation registered is demonstrated graphically in Fig. 1 as the total test scores for all patients tested with each material. The means for each material are also given (Table 1).

Stomahesive caused the lowest number of responders at 1 h and 24 h. With a non-parametric test Stomahesive gave significantly ($p < 0.01$) lower score values at 1 h than all the other tested adhesives. At 24 h, Stomahesive's score was

significantly lower than for Urax ($p < 0.01$) and Coloplast extra ($p < 0.05$); Coloplast gave the highest score, being significantly higher at 1 h than Stomahesive ($p < 0.01$), Urax ($p < 0.05$), Uretesan ($p < 0.01$), Mitcham ($p < 0.01$) and Chiron ($p < 0.01$). At 24 h the score was still significantly higher ($p < 0.05$) than Stomahesive and Uretesan. The error of the method (*left-right comparisons*) was 11%.

Discussion

Several methods have been published concerning methods for assessing irritancy of topically applied materials [5]. The procedure used in this study was a patch test model with

application to normal skin for 2 days. It has earlier been found to be a sensitive method for discriminating skin irritating and adhesive characteristics of adhesive tapes [7]. It may not, however, be as sensitive as the chamber scarification test for assessing slight irritation potential [5]. The overall irritant scores were low. The present study demonstrated, however, differences between the different types of stomal adhesives in their ability to induce irritancy. Thus, the adhesive disc made of pectin, gelatine and sodium carboxymethylcellulose (Stomahesive) was significantly less irritating than the others. Another sort of adhesive disc with polyacrylate as adhesive material, Uretesan, had lower irritant scores than some of the adhesives of the third type, i.e. those with a rubber-based adhesive mass. This finding corroborates the results of a study using repeated replacements for 3 weeks of adhesive plasters from stoma appliances [8].

In clinical usage, the inflammatory response under the adhesive is dependent on many variables (see introduction), one of which is the adhesive itself. The material in the adhesive mass seems to be more important than the frequency of removal [8]. In patients with peristomal skin problems, a change to a low-irritating adhesive is advisable in combination with an attempt to eliminate as many as possible of the other contributing factors. However, we found that adhesive discs of pectin-gelatine must be changed daily or every second day as they seem to be dissolved in urine within 24–48 h with a possible subsequent leakage of urine and harmful effects of urine upon the skin (unpublished observations). Thus this type of adhesive is the one of choice when major peristomal skin complications are present, such as papillomatous lesions [1] or acute eczema. When less severe lesions are present an adhesive disc with a polyacrylate-based adhesive mass might be preferable. As most adhesive discs available have rubber as the adhesive mass, and this material seems to be the less tolerable type, it is hoped that more low-irritating artificial materials will be developed.

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Dr. B. Bergman
Dept. of Urology
University of Umeå
S-901 85 Umeå
Sweden