Prosthetics and Orthotics International, 1996, 20, 172-175

The use of Methenamine as an antiperspirant for amputees

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Abstract

The socket of a prosthesis is a tightly closed container. Sweating inside the socket is annoying and may also irritate the skin over the stump or lead to local infection such as folliculitis. The most effective method of preventing sweating is by the use of astringent agents. Formaldehyde is a very strong astringent but is not pleasant to use and may cause skin irritation and systemic reactions. Methenamine, in water or when applied to the skin, decomposes to generate formaldhyde in small quantities which do not cause side effects. Methenamine was used on the stump of sixteen amputees. The trial was conducted as a double blind study using two different solutions market as solution A and as solution B. The effectiveness , of the solutions as an antiperspirant was evaluated clinically by the subjects and the physician. Solution A containing Methenamine, was found significantly effective, both by the subjects and physician when compared with the solution B the blank one. The use of Methenamine as an antiperspirant is recommended in amputation stumps.

Introduction

A prosthetic socket is a closed container usually made of plastic materials. Sweating within the socket is considerable, especially in hot countries. In addition to the unpleasantness, sweating may cause damage to the skin of the stump; evaporation is impaired in the closed socket, the sweat collects and becomes a growth medium for bacteria. Also, the properties of the skin are changed and danger of abrasion and infection increases (Levy, 1983).

Several techniques were tried to prevent or decrease sweating of the stump inside the socket. Mechanical methods such as fabrication of the socket from porous material or drilling holes in it are not very effective. Pharmacological methods including creams of botanical origin have only a soothing effect on the skin. Anticholinergic drugs such as Probanthine have been proposed (Rollinson, 1971). As there are no preparations available for use on the skin it was proposed to crush pills, mix the powder with talcum and apply to the stump. The value of this method has not been proven.

An effective method to prevent sweating is the use of agents which have an astringent effect on the sweat glands (Walker and Swafford, 1971). Salts of aluminium and zinc are in wide use in deodorants but their astringent action is very weak (Rollinson, 1971). Formaldehyde is a material with very strong astringent action. Application of a solution of 3% formaldehyde once or twice is enough to prevent sweating for a prolonged period. However, formaldehyde is contraindicted because of the danger of allergic reactions and its strong odour (Rollinson, 1971). Methenamine (Fig. 1) is a chemical substance which converts into formaldehyde in water or in an acid environment (Cullen, 1975; Goodman and Gilman, 1975; Rollinson, 1971). It is usually used in treatment or prevention of urinary tract infections in cases of spinal cord injury, administered orally in a dose of 2-4 gr daily. As

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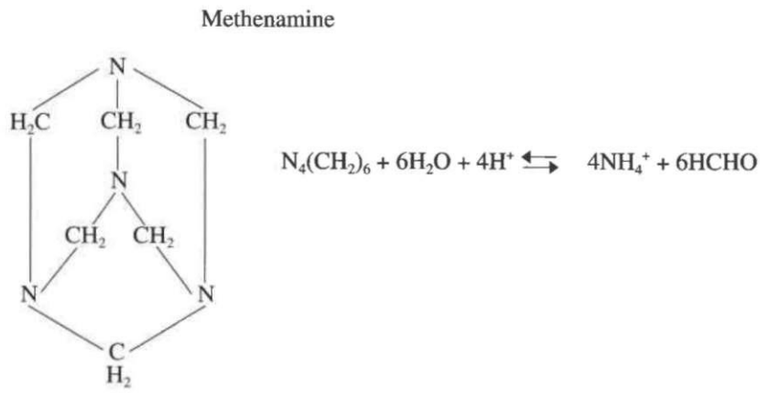

Fig. 1. Methenamine decomposes in water to generate formaldehyde.

a result, the bactericidic effect of formaldehyde can be used without danger for topical application. Methenamine was found effective in the treatment of hyperhidrosis (Cullen, 1975).

On the basis of these considerations a solution was prepared and a double blind study has been conducted to test its antiperspirant effectiveness on amputation stumps.

Subjects and methods

Sixteen amputees, four female and twelve male, participated in the study. Eleven were trans-femoral amputees and five trans-tibial amputees. All suffered from a considerable sweating of the stump inside the prosthetic socket, especially during the summer. Their mean age was 43.5±7.1 with range 27-52 years. Mean time since amputation was 11.2±5.2 years with range 3-12 years. All were excellent users of their prosthesis and apart from excessive sweating they did not suffer from stump problems or difficulties in fitting of the prosthesis.

The solution provided to the subjects were either active solutions (A) containing Methenamine or blank solutions (B) without Methenamine. The formula of the active substance was: Methenamine 25 gr, Alcohol 95% 52.6 ml, Aqua Distilata ad to 250 ml. The blank solution contained: Alcohol 95% 52.6 ml, Aqua Distilata ad to 250 ml. The solutions were supplied by the pharmacist in 100 ml identical bottles marked by numbers.

The study lasted for two years. The main period of treatment took place in the summer months. The subjects were instructed to apply the solution to the stump each evening and let it dry. They were instructed to continue the treatment until the entire solution (one bottle of 250 ml) had been used even if they did not experience any effect. In total 96 bottles of solution were supplied. Every subject received six bottles, three per year. Whenever a subject used up a bottle, he visited the outpatient clinic and informed the physician on the usefulness of the treatment.

The subjects were asked to wear their prosthesis continuously, for at least 2 hours, prior to evaluation. In the examination room, the subject took off his prosthesis and the stump was evaluated for level of sweating as follows; first - the subject's feeling of reduction of sweating, second - the physician's examination and impression on amount of stump sweating. The results were graded as; 1 - poor or no antiperspirant effect, 2 - moderate effect, 3 - excellent effect. None of the subjects reported negative side effects such as rashes, allergies, or skin breakdown manifested during the period of usage of the solutions. When the study was completed the code of the bottles was broken. The grades of effectiveness attributed by the subjects and the physician to solutions A and B were matched. The active solution was tested after twelve months and it was found to remain stable when stored in a glass bottle.

Statistical analysis was performed by the SAS computer programme using T-test and probability (Cary, 1989).

Results

After the code of the bottles was broken the results of the effectiveness of each bottle, as

Table 1. Antiperspirant activity of solution A and B as evaluated by the patient and physician (raw results after the code of the bottles was broken), sol. - solution, S - subject, P - physician.
1 - Poor or no antiperspirant effect, 2 - Moderate effect, 3 - Excellent effect.
A - Active solution (containing Methenamine), B - Black solution (without Methenamine).

Subject	Amput. level	Bottle 1 sol. - S - P	Bottle 2 sol. - S - P	Bottle 3 sol. - S - P	Bottle 4 sol. - S - P	Bottle 5 sol. - S - P	Bottle 6 sol. - S - P
1	AK	B - 1 - 1	B - 2 - 1	A - 3 - 3	A - 3 - 3	A - 3 - 3	A - 2 - 3
2	AK	B - 2 - 1	B - 1 - 2	B - 1 - 2	A - 3 - 3	A - 3 - 3	B - 1 - 1
3	AK	A - 2 - 3	B - 1 - 1	A - 3 - 3	B - 1 - 2	B - 1 - 2	A - 3 - 3
4	AK	A - 3 - 2	A - 3 - 3	B - 2 - 1	B - 1 - 1	A - 2 - 3	A - 3 - 3
5	BK	B - 2 - 1	A - 3 - 3	B - 1 - 2	A - 3 - 3	A - 3 - 3	B - 3 - 2
6	BK	B - 1 - 1	A - 3 - 3	B - 3 - 2	A - 3 - 3	B - 1 - 1	B - 3 - 2
7	AK	B - 1 - 1	A - 3 - 3	B - 1 - 1	A - 3 - 3	A - 3 - 2	A - 3 - 3
8	AK	A - 2 - 3	B - 1 - 2	A - 3 - 3	A - 3 - 2	A - 3 - 3	B - 1 - 1
9	BK	B - 2 - 1	A - 3 - 3	A - 3 - 3	B - 3 - 2	B - 1 - 2	B - 1 - 1
10	AK	B - 1 - 1	A - 3 - 3	B - 1 - 1	A - 3 - 3	A - 2 - 3	B - 1 - 2
11	AK	B - 1 - 1	B - 1 - 1	A - 3 - 2	B - 2 - 1	B - 1 - 1	A - 3 - 3
12	BK	A - 3 - 3	A - 3 - 3	B - 2 - 1	A - 3 - 2	B - 1 - 1	A - 3 - 3
13	AK	A - 3 - 2	A - 3 - 3	B - 1 - 2	B - 1 - 1	A - 2 - 3	A - 3 - 2
14	BK	A - 3 - 3	A - 3 - 2	A - 3 - 3	B - 3 - 1	B - 1 - 1	B - 2 - 1
15	AK	B - 1 - 1	B - 2 - 1	A - 3 - 3	B - 1 - 1	A - 3 - 3	A - 2 - 3
16	AK	A - 3 - 3	A - 3 - 3	B - 1 - 1	A - 2 - 3	B - 1 - 1	A - 3 - 3

graded by the subjects and the physician, were matched (Table 1). The normalised factors (Table 2) represent the average grades (total grades divided by total number of bottles) attributed by the subjects and by the physician to bottles marked A and B. Table 3 presents the final normalised factors obtained in each of the compared groups; subjects, physician, solution A, solution B. The final normalised factors represent the sum of the obtained normalised factors divided by the total number of the subjects.

The effectiveness of the treatment (final normalised factors) attributed to solution A and

Table 2. Values of total bottles, total grades, and normalised factor obtained for solution A (containing Methenamine) and for solution B (without Methenamine). The normalised factor is obtained by dividing total grades by the total number of bottles.

	Solution A					Solution B				
	Subject			Physician		Subject			Physician	
Subject	Total bottle	Total grades	Normal. factor	Total grades	Normal. factor	Total bottle	Total grades	Normal. factor	Total grades	Normal. factor
1	4	11	2.750	12	3.000	2	3	1.500	2	1.000
2	2	6	3.000	6	3.000	4	5	1.250	6	1.500
3	3	8	2.666	9	3.000	3	3	1.000	5	1.666
4	4	11	2.750	11	2.750	2	3	1.500	2	1.000
5	4	12	3.000	11	2.750	2	2	1.000	2	1.000
6	4	11	2,750	11	2.750	2	2	1.000	3	1.500
7	3	8	2.666	9	3.000	3	3	1.000	4	1.333
8	2	6	3.000	5	2.500	4	5	1.250	4	1.000
9	4	11	2.750	10	2.500	2	2	1.000	3	1.500
10	3	8	2.666	9	3.000	3	4	1.333	3	1.000
11	4	11	2.750	12	3.000	2	2	1.000	2	1.000
12	3	9	3.000	9	3.000	3	6	2.000	5	1.666
13	2	6	3.000	6	3.000	4	8	2.000	6	1.500
14	2	6	3.000	6	3.000	4	7	1.750	6	1.500
15	4	12	3.000	11	2.750	2	3	1.500	2	1.000
16	3	9	3.000	8	2.666	3	6	2.000	3	1.000

Table 3. Comparison between the final normalised factors (the sum of the normalised factors divided by the total number of subjects) obtained for each of the groups.

	Solution A	Solution B	p<
Subjects	2.859±0.14	1.380±0.38	0.001
Physician	2.854±0.18	1.260±0.27	0.001
p	ns	ns	

solution B by the subjects was compared with that of the physician (Table 3). No significant differences were found between the evaluations of the subjects and the physician for solution A and solution B. The difference between solutions A and B was found highly significant when evaluated by the subjects (p<().()01) and by the physician (p<0.001).

Discussion

A double blind study on the effectiveness of Methenamine as an antiperspirant in amputation stumps is reported. Although the evaluation of the solutions was made subjectively by the amputee and by the physician it is assumed to be reliable because there was no difference between the two evaluations. On the other hand there was a strong significant difference between the solution containing Methenamine and the solution without it.

It is therefore concluded that Methenamine is an effective antiperspirant and is recommended for use on amputation stumps. Although no allergic reactions were noted in the trial, it is noted that allergic reactions are not uncommon and vigilance should be maintained.

Acknowledgement

The authors would like to thank Mr. E. Yucha for his help in the statistical evaluation.

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