

# Sulfamylon Therapy in Severe Burns: Two Hundred Forty-Six Cases Compared to Previous Experience

B. W. HAYNES, JR., M.D., WILLIAM E. GAYLE, JR., M.D.,  
G. E. MADGE, M.D.

*From the Departments of Surgery and Pathology, Medical College of Virginia,  
Richmond, Virginia*

THE control of wound infection in burns has been the subject of many experiments which have also included the use of enteral and parenteral agents of the antibiotic era. These therapeutic approaches have produced some gains but have not resulted in significant infection control.

The use of aqueous 0.5% silver nitrate locally by Moyer *et al.*<sup>8</sup> and Sulfamylon Hydrochloride (10%) ointment by Moncrief *et al.*<sup>7</sup> demonstrated the capability of these agents to reduce total bacterial counts in burns to very low levels. Both reported significant decreases in mortality as a result. Complications of both drugs appeared controllable and both investigative groups were enthusiastic. The fundamental importance of dead tissue in burn wound infection was clearly reaffirmed by both groups noting that effective local bacterial control resulted in prolonged separation of the dermal slough. The crucial nature of this point will be re-emphasized by our study.

On the basis of these and other available data, we selected Sulfamylon Acetate 10% for study beginning 1 January 1966, and, after a brief alternate case trial, elected to use the agent on all patients with third degree and questionable deep dermal injuries admitted to the Burn Unit of the Medical College of Virginia. Obvious second degree burns were treated by exposure therapy without Sulfamylon. The only limitation on size of burn treated was that im-

posed by the need for hospitalization; no outpatients were treated with Sulfamylon. On this basis, 246 patients have been treated from 1 January 1966 through 31 December 1968.

## Methods

Patients presenting for treatment were evaluated for respiratory and circulatory function and treated accordingly. Fluid and electrolyte replacement therapy was guided by the Evans Formula and details of this treatment have been recorded elsewhere.<sup>4</sup> In general, fluid therapy has been successful characterized by good circulatory support and preservation of satisfactory organ function.

Initially, devitalized epidermis was removed and blisters excised. General cleansing with pHisoHex and warm saline solution followed. On all third degree burns and deep second degree burns, a thin layer of Sulfamylon cream was applied with a gloved hand. Wound care consisted of tub or whirlpool tap water baths for 30 minutes morning and afternoon with debridement after each bath and the application of Sulfamylon cream. Wound cultures were performed on all patients twice weekly and sensitivity data obtained. Prophylactic penicillin was used to prevent beta hemolytic streptococcal infection. The indication for enteral or parenteral antibiotic therapy was serious burn wound infection as judged by the patient's general condition, especially central nervous system function,<sup>3</sup> white blood count and dif-

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ferential, body temperature, and the presence of paralytic ileus. Pneumonitis, urinary tract infection, and thrombophlebitis were specific indications for selective antibiotic therapy. On these bases, colistomethate (Colymycin) was selected most commonly but kanamycin, Polymyxin B, and others were employed.

Under this regime, wounds re-epithelialized in 2 to 3 weeks in most partial thickness injuries. The third degree burns required longer periods of time to separate and granulate. Skin grafting was performed usually within 6 weeks postburn, but in several instances delays in wound separation up to 8 to 10 weeks were encountered, particularly in extensively burned older patients. Children, characteristically, separate their dead tissue more quickly than adults. In order to hasten separation of slough, after 2½ weeks the edges of the third degree burn were treated with non-antibiotic ointment dressings selectively to, in effect, increase bacterial growth and bacterial debridement in a restricted area. This maneuver produced more rapid tissue separation permitting more effective daily sharp debridement. Selective bacterial wound management as described is useful especially in the extensively burned older patient, but must be applied judiciously so as not to overwhelm the patient with an increased bacterial load. In this regard, the signs of early burn coma<sup>3</sup> are useful as an index of decompensation of resistance in the face of increasing infection.

Mortality data on the 246 patients in this series are presented on Tables 1 and 2 as compared to a series of 1,831 patients treated from 1949 to 1962 at our unit.<sup>9</sup> Pre-Sulfamylon local therapy included occlusive dressings and exposure primarily. Prophylactic penicillin therapy has been standard throughout both series, but parenteral antibiotic therapy evolved as drugs became available. Fluid therapy, emphasis on good nutrition, and good nursing care have been relatively consistent throughout.

## Results and Discussion

Tables 1 and 2 compare the Sulfamylon treated series to previous experience on the basis of per cent total body surface area of burn (Table 1), third degree burn (Table 2), and age as they affect mortality. At the far right side of each table, per cent mortality is compared between the pre-sulfa series and the Sulfamylon series by percentage groups of total area of burn of all ages. On Table 1, for example, patients with 15 to 24% burn showed no significant change in mortality, and patients with 25 to 34% burn were comparable in both series. It is with burns of this approximate size that the most significant reductions in mortality have occurred in the U. S. Army Surgical Research Unit series.<sup>6</sup>

If one examines the group with burn of 25 to 34% with regard to age distribution, it becomes apparent that the mortality rate in the 0 to 4 year group and the 5 to 14 year group was approximately ½ that of the pre-Sulfamylon series. In the 25-34% group, there were a total of 142 cases with 65 deaths in the pre-Sulfamylon series, and 36 patients and 16 deaths in the Sulfamylon series. In the 40 to 44 year group, the Sulfamylon mortality is 50% compared to 27% but there were two patients only in the Sulfamylon group. In the 45-64% group the mortality with Sulfamylon was lower than with previous treatment (33% vs. 55%). It will also be observed that the case numbers in the individual age group are small making definite conclusions concerning age and mortality untenable. Comparing all patients in both series with 25-34% total burn, which should show most improvement, no appreciable change in mortality was observed. Similar comparisons are made on Table 2 with regard to third degree burn. Mortality, listed by per cent of third degree burn, shows no improvement with Sulfamylon. In fact, in the first three categories, namely, 1 through 24%, they are considerably higher. The same criticisms apply to this table as to

TABLE 1. Sulfamylon Burn Therapy: 246 Cases

% Total Area Burn	0-4 Years				5-14 Years				15-39 Years			
	Patients		Mortality %		Patients		Mortality %		Patients		Mortality %	
	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa
0-4	107	0	0	0	59	0	0	0	121	2	0	0
5-14	232	8	1	0	86	6	0	0	167	14	0	0
15-24	79	12	4	0	56	5	7	0	86	13	4	0
25-34	31	5	39	20	24	5	42	20	37	9	27	22
35-44	16	8	69	75	23	6	52	67	24	7	46	29
45-54	9	4	78	75	7	3	71	100	18	7	50	57
55-64	11	2	100	100	9	5	78	100	15	4	80	100
65-74	2	0	100	—	4	0	75	—	12	3	83	67
75-84	1	0	100	—	3	0	100	—	9	0	100	—
85-94	3	0	100	—	2	0	100	—	13	3	100	100
95+	2	0	100	—	2	0	100	—	3	0	100	—
Totals	493	39	11	31	276	30	18	43	505	62	16	27

the previous one, that is, the numbers of patients broken down by age groups are small but no favorable trend in the Sulfamylon treated younger age groups is observed as in the previous table.

Table 3 summarizes data on topical burn therapy from MCV, U. S. Army Institute of Research (Surgical Research Unit) and Dr. William Monafó of St. Louis, and points out the excellent result obtained at the Surgical Research Unit and by Dr. Monafó in comparison with our data. There are several differences between these case series which might serve as partial explanations for the observed differences. The largest difference is, of course, the patient population at the SRU compared to MCV. The SRU population consisted of

healthy, well-nourished adults of military age plus children whereas at MCV the population is a broad spectrum of young and elderly (47% age 40 and over) often from a low socio-economic level with frequent nutritional problems and degenerative disease. Our patients are more like those of Dr. Monafó than those of the Surgical Research Unit as is our mortality data. Other variables difficult to evaluate include the use of skin homografts as a biologic dressing changed every 4 days at the Surgical Research Unit, a technic we have not used significantly, and a higher personnel to patient ratio. None of these comparisons apply, of course, to our own two series of cases. In fact, our two series comparison is weighted against Sulfamylon

TABLE 2. Sulfamylon Burn Therapy: 246 Cases

% 3rd Area Burn	0-4 Years				5-14 Years				15-39 Years			
	No. Patients		% Mortality		No. Patients		% Mortality		No. Patients		% Mortality	
	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa
1-4	159	6	3	0	86	6	0	0	154	13	0.6	0
5-14	69	13	7	15	50	6	6	33	76	22	7	18
15-24	21	8	29	50	29	3	24	0	33	6	24	50
25-34	18	2	67	100	21	7	57	71.4	24	4	67	75
35-44	6	2	83	50	13	4	69	100	9	3	78	67
45-54	11	1	91	100	8	1	75	100	12	1	67	100
55-64	3	0	100	—	4	1	75	100	14	2	100	100
65-74	2	0	100	—	4	0	100	—	8	0	100	—
75-84	1	0	100	—	1	0	100	—	4	1	100	100
85-94	4	0	100	—	3	0	100	—	5	0	100	—
95+	0	0	—	—	1	0	100	—	2	0	100	—
Totals	294	32	18	31	220	28	22	46	341	52	24	31

(1966-1968) Compared to 1831 Cases (1949-1962)

40-44 Years				45-64 Years				65+ Years				Mortality %	
Patients		Mortality %		Patients		Mortality %		Patients		Mortality %		By % Burn	
Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa
27	1	7	0	74	2	3	0	62	3	18	33	3	12
27	5	4	0	112	14	5	7	57	12	40	42	5	10
5	2	0	0	39	14	31	21	21	6	71	84	13	15
11	2	27	50	20	6	55	33	19	9	100	100	46	44
4	2	100	0	8	7	75	71	9	6	100	100	63	64
2	4	100	100	13	6	100	100	6	1	100	100	76	84
2	2	100	100	5	0	80	—	6	1	100	100	88	100
3	0	100	—	5	1	100	100	2	3	100	100	89	86
4	0	100	—	1	3	100	100	2	1	100	100	100	100
0	0	—	—	4	0	100	—	2	2	100	100	100	100
0	0	—	—	1	0	100	—	4	0	100	—	100	—
85	18	25	39	282	53	23	40	190	44	52	77	20.2	42.2

by virtue of increased age of the burned population. In the pre-Sulfamylon group, 26% of patients were 45 years and older, whereas in the Sulfamylon group, 39% was 45 years and above. This age group accounted for 44% of deaths in the pre-Sulfamylon group, and 53% of deaths in the Sulfamylon treated group. This factor is unquestionably important in evaluating mortality rates. Winkley *et al.*<sup>11</sup> observed mortality rates after Sulfamylon similar to ours, and emphasized the differences between their population (Los Angeles County Hospital) and the Surgical Research Unit group. In their patients, nutritional deficiency, alcoholism, and cardiovascular disease were frequently observed.

In order to gain another comparison, a series of pre-Sulfamylon septicemia pa-

tients treated at MCV were compared to those occurring in the Sulfamylon series. These data are summarized on Table 4. Fifty-five pre-Sulfamylon septicemia patients compared to sixty-three Sulfamylon treated patients developing septicemia showed no significant differences in age, per cent total burn, or per cent third degree burn. The per cent survival in the pre-sulfa group was 13 and the sulfa group 16. This difference is not considered to be significant. The organisms cultured from the blood stream are listed on Table 5. In the pre-Sulfamylon group, pseudomonas was present 38% of the positive blood cultures whereas in the Sulfamylon treated group only 24%. Klebsiella Aerobacter, being only 12% of the pre-Sulfamylon septicemias now rose to 46% to become the lead-

(1966-1968) Compared to 1831 Cases (1949-1962)

40-44 Years				45-64 Years				65+ Years				Mortality %	
No. Patients		% Mortality		No. Patients		% Mortality		No. Patients		% Mortality		By % Burn	
Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa	Pre-Sulfa	Sulfa
31	6	0	0	95	10	4	10	63	10	19	40	3.71	9.8
13	5	15	20	71	18	17	28	53	13	66	77	18.9	31
5	1	40	100	24	9	67	44	12	8	100	100	41	60
3	2	100	50	11	4	100	75	12	3	100	100	74	77
3	2	100	100	5	4	100	100	8	2	100	100	84	76
3	1	100	100	11	2	91	100	5	2	100	100	84	100
1	1	100	100	2	1	100	100	4	3	100	100	96	100
1	0	100	—	1	0	100	—	1	1	100	100	100	100
4	0	100	—	2	1	100	100	1	1	100	100	100	100
0	0	—	—	2	0	100	—	2	0	100	—	100	—
0	0	—	—	0	0	—	—	3	0	100	—	100	—
64	18	30	39	224	48	29	42	164	43	58	79	27.5	45

TABLE 3. Comparison of Burn Data from Three Centers

Total Burn %	MCV <sup>1</sup> 25-34	S.R.U. <sup>2</sup> 31-40	Manaf <sup>3</sup> 31-40
Patients	36	119	22
Deaths	16	14	6
Mortality	44%	12%	27%

<sup>1</sup> Sulfamylon—Medical College of Virginia.  
<sup>2</sup> Sulfamylon—U. S. Army Institute of Research.  
<sup>3</sup> Silver Nitrate—Dr. William Monaf—St. Louis.

TABLE 4. Septicemia in Severe Burns

	Pre-Sulfamylon	Sulfamylon
Patients	55	63
Age (average)	34	37
Total burn %	42	43
3° burn %	31	27
Survival (%)	13	16

ing cause of sepsis. Other organisms increasing in frequency included *E. coli* and candida. Paracolon, *S. aureus*, Herellea and Proteus decreased in frequency.

At the same time we observed prolonged separation of the slough following the use of Sulfamylon we also observed significant sepsis occurring beyond the first month after injury. Figure 1 is a comparison of the two series of septicemia patients according to day postburn when positive blood cultures were observed. The peak incidence of septicemia in both series occurred about the end of the first week and

TABLE 5. Septicemia in Severe Burns

Organisms	Pre-Sulfamylon (55 Pts.)	Sulfamylon (63 Pts.)
Pseudomonas	38%	24%
Klebsiella-aerobacter	12	46
Paracolon	17	1
<i>S. aureus</i>	16	7
<i>H. vaginalis</i>	10	0
Proteus	5	3
<i>E. coli</i>	0	10
Candida	0	3

TABLE 6. Septicemia in Severe Burns

	Length of Hospitalization (days)	
	Pre-Sulfamylon	Sulfamylon
Survivors	45	73
Non-survivors	16	29

continued in similar frequency until about 3 weeks postburn. Beyond 3 weeks, however, the septicemias were observed, for the most part, in the Sulfamylon treated group correlating, it would appear, with the presence of the dermal slough and its prolonged separation. Deaths beyond 45 days postburn (five patients) were all in the Sulfamylon group.

Table 6 points out the relationship between Sulfamylon therapy and the length of hospitalization. In patients surviving septicemia in the pre-Sulfamylon series,

SULFAMYLON EFFECT ON POSITIVE BLOOD CULTURES

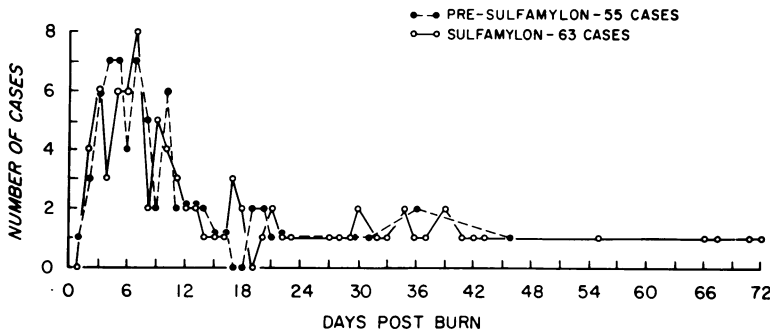


FIG. 1. Septicemia beyond 3 weeks occurred almost entirely in the sulfamylon series and appears to correlate with delayed separation of dead tissue.

TABLE 7. *Sulfamylon Burn Therapy: Length of Hospitalization*

	Exposure Therapy Total Admissions	M	F	Hospitalization (Av.)	Deaths	Mortality
1964	194	124	70	21 days	35	18%
1965	226	150	76	21 days	42	18.5
	Sulfamylon Therapy Total Admissions	M	F	Hospitalization (Av.)	Deaths	Mortality
1966	245 (sulfa-treated 54)	164	81	23 days	37	17.9%
1967	207 (sulfa-treated 101)	124	83	30 days	45	21.7
1968	200 (sulfa-treated 91)	118	82	27 days	52	26
	Sulfamylon Group Only Total Admissions	M	F	Hospitalization (Av.)	Deaths	Mortality
1966	54	33	21	35 days	22	40%
1967	101	58	43	41 days	41	41
1968	91	51	40	40 days	41	45

the average length of hospitalization was 45 days compared to 73 days in the Sulfamylon series. In the non-surviving patients, before Sulfamylon, a 16-day average hospital period was observed, whereas in the Sulfamylon series this had been lengthened to 29 days, indicating a prolonged survival. A broader look at length of hospitalization is provided by Table 7, where exposure therapy and Sulfamylon therapy are compared. During 1964-65, average hospitalization of all admissions was 21 days. In 1966-68, when Sulfamylon was increasing in usage, the overall hospitalization rose 23, 30, 27 days consecutively. When the Sulfamylon group is separated from the total, the hospitalization times became 35, 41, and 40 days. While one expects slower separation of dead tissue in larger than in smaller injuries selectively treated with Sulfamylon, comparison of total admissions before and after Sulfamylon plus clinical observation points out the truly significant problem associated with Sulfamylon, i.e., prolonged separation of dead tissue. In spite of the fact that the numbers of organisms are reduced significantly in the wound by Sulfamylon ( $10^8$  to  $10^4$  per gram of tissue approx.), a marked delay in wound separation and

subsequent grafting leads to increased morbidity and in some instances, increased mortality. Indeed there seems to be little doubt that five Sulfamylon-treated patients dying of septicemia beyond 45 days postburn are a precise illustration of the problem. In substance we believe the lack of mortality improvement in our series must bear a significant relationship to the resultant wound slough delay, with delay in skin grafting and wound healing. When wound excision of 3° burn can be accomplished, significant improvement in morbidity and shortened healing time characteristically results.<sup>2</sup>

Surgical debridement of the extensive burn is fraught with danger of developing over-whelming infection and shock. However, judicious debridement daily after tubbing, and selective operating room debridement offer help. It seems clear that the larger burn, especially in the older, debilitated patient badly needs a more effective means of slough removal followed by early grafting.

Other complications of Sulfamylon therapy include skin rash, pain on application, and carbonic anhydrase inhibition. Rash has been an uncommon problem observed in four patients in the series requiring dis-

TABLE 8. *Causes of Death—104 cases*

	0-14 years	15-44 years	45-64 years	65+ years
Early (5 days)	6 patients	7 patients	4 patients	13 patients
Sepsis (septicemia)	1	2	1	5
Pulmonary	3 (one septic)	2	2	4
Cardiovascular				
Myocardial infarction				2
Congestive heart failure	1 (low platelets)	1	1	
Thromboembolism				
Metabolic		2		
Unknown	1			2
Late (beyond 5 days)	18 patients	16 patients	17 patients	23 patients
Sepsis (septicemia)	12	13	10	11
Pulmonary	2	2	2	3
Cardiovascular				
Myocardial infarction				2
Congestive heart failure	2		1	3
Thromboembolism			1	1
Gastrointestinal	2 (Curling's ulcer)		1 (perforated ulcer)	
Metabolic		1 (liver failure)	2	2 (Renal failure acidosis)
Unknown				1

continuance of the drug. Pain on application is common, usually managed without stopping the drug, and is most troublesome in smaller injuries, e.g., hand burns. Carbonic anhydrase inhibition of renal tubular cells, red blood cells and other tissues results in increased respiratory rates and CO<sub>2</sub> excretion. Resultant respiratory alkalosis, commonly observed, is of minor significance unless pneumonitis or atelectasis supervene and is complicated by development of metabolic acidosis (renal, lacticacidemic). This series of events is typically associated with severe sepsis.

Of the Sulfamylon treated group, there were 104 deaths with autopsy data on 45 cases (Table 8). The predominant cause of death was sepsis, primarily wound sepsis. Many of the patients dying from organ failure (pulmonary, cardiovascular, renal)

had burn wound sepsis as a major contributing cause of death. Sepsis listed as a cause of death means septicemia. Early pulmonary deaths were essentially respiratory chemical injury (smoke inhalation) and late pulmonary deaths were respiratory injury and pneumonitis. Two cases of thromboembolism were noted. Over one third of the deaths were in the 65 plus age group and cardiovascular problems contributed significantly to the causes of death.

One of the more interesting pathologic observations was the presence of hyaline membrane formation in the alveoli of the lung. Of 45 cases, hyaline membranes were observed in 13 (29%), with many alveoli involved in 6. Other changes included alveolar cell desquamation, thickening of the alveolar wall with many macrophages

and often hemorrhage. The genesis of hyaline membrane is in doubt in these cases,<sup>1, 5, 10</sup> since many received oxygen therapy in high concentration (40%). All received Sulfamylon topically<sup>5</sup> and showed varying degrees of pneumonitis. There was no vasculitis or arteritis to suggest hypersensitivity to Sulfamylon in the lung sections studied. A more detailed account of the pathologic findings will be published elsewhere.

### Summary

Two hundred forty-six Sulfamylon treated thermal burns have been compared to a previous experience of 1,831 patients. In a burn population of young and old patients (47% age 40 and over), trends suggesting improved mortality in young patients were seen, but no overall mortality improvement was observed. There were more older patients in the Sulfamylon group which weighted the comparison against Sulfamylon. Burn wound sepsis and septicemia was the leading cause of death, with pulmonary and cardiovascular causes following.

The ability of Sulfamylon to decrease local bacterial counts was observed, and resultant prolonged separation of the dead tissue appears to play a major role in mortality in the Sulfamylon group.

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### DISCUSSION

DR. JOHN ARTHUR MONCRIEF (Charleston): I would agree with many of the things that Dr. Haynes has said and take issue with some others, and I hope that it is not as great an issue as we have seen earlier.

(Slide) As Dr. Haynes has mentioned, the problem of change of the frequency of bacteria flora qualitative change has been noted previously. After one year of use of Sulfamylon in the surgical research unit, the *Aerobacter* rapidly began gaining in prominence and now, as Dr. Haynes reported, does indeed outnumber in frequency the *Pseudomonas*. However, it has not be-

come a major pathogen as far as increasing mortality rates are concerned.

(Slide) One can certainly reduce the numbers of bacteria in the barren wound with any type of effective topical therapy, whether one uses Sulfamylon, silver nitrate, gentamycin or anything else, one has by no means sterilized the wound; you have merely reduced the bacterial count to more manageable levels.

But these levels are more manageable for limited periods of time, the limits of which are undetermined. Actually, I think it is reasonable for us to assume that if the individual is constantly exposed, to even a reduced level of bacterial colonization for this long period of time,