

RESULTS

R E S U L T S

In this study 30 patients were included, 23 men and 7 women. Their age ranged between 19 and 65 years with an average of 47.43 years. All cases chosen were in acute exacerbation of chronic bronchitis as evidenced by expectoration of purulent sputum.

Fifteen were treated with Lidaprim 'Trimethoprim-sulphamethoxazole' group I, and fifteen with Septrin ('Trimethoprim-sulphamethoxazole' group II). 3 women and 12 men were included in group I. Their age ranged between 24 - 65 years old with an average of 50.4 years. 4 women and 11 men were included in group II, their age ranged between 19-65 years old with an average of 44.46 years.

Bacteriological study of the patients' sputa revealed 7 different types of bacteria in variable combinations. Table(1) shows the pattern of organisms isolated in the initial culture.

Table (1) : Pattern of organisms isolated in
initial cultures .

Case	Age	Sex	B-Haem. strept.	Staph aureus	H.Inf- luenza	Colon group bacilli	Neis- seria	Diph- ther-	Mic- roco- oids	ccus
1	62	M	+				+			
2	65	M	+				+			
3	45	F	+				+	+		+
4	40	M	+		+					
5	19	M	+				+			
6	43	M	+	+			+			
7	40	F		+			+			
8	62	M	+				+			
9	55	M				+				
10	64	F	+		+		+			
11	24	M	+	+			+			
12	55	M	+	+			+			+
13	55	M	+	+			+			
14	25	F		+			+			
15	35	M		+				+		
16	65	M			+		+			
17	45	F		+			+			
18	31	M		+			+			
19	21	M	+	+			+			
20	62	M	+				+			
21	55	M	+							
22	50	M		+			+	+		
23	55	M	+	+			+			
24	25	F		+			+			
25	65	M	+				+			
26	30	M		+			+			
27	55	M	+				+			
28	55	F	+				+			
29	55	M	+				+			
30	65	M	+				+			

Table (2) : Frequency of different organisms
initially isolated

Organisms	No. of cases	Percentage
1. B-Haemolytic streptococci	20	66.66 %
2. Staph aureus	14	46.66 %
3. Haemophylus influenzae	3	10.00 %
4. Bacilli of the colon groups	1	3.33 %
5. Neisseria	26	86.66 %
6. Diphtheroids	3	10.00 %
7. Micrococci	2	6.6 %

As seen in table (2) ,which shows the frequency and percentage of the initially isolated organisms, B-haemolytic streptococci were the most prevalent pathogenic organism. They were initially isolated in 20 cases (66.66 %). Staph-aureus was isolated in 14 cases (46.66 %). Coagulase test was positive in the 14 cases suggesting the pathogenicity of isolated staph.aureus.

H.Influenzae were isolated in 3 cases (10 %). In ~~one~~ case it was isolated with neisseria and in 2 cases with B-haemolytic streptococci. Pure culture of colon group bacilli was isolated in one case (3.33 %). Diphtheroids were identified in 3 cases (10 %) and micrococci in 2 cases (6.6 %).

It seems that neisseria were common denominators being present in 26 cases out of 30 (86.66 %) in addition to one or

more pathogenic organisms.

The pattern of distribution of organisms initially cultured in cases treated with Lidaprim (group I) and those treated with Septrin (group II) are demonstrated in table (3) and (4) respectively.

Table (3) Pattern of organisms initially culture
(group I cases)

Case No.	Age year	Sex	B.Haem. Strept.	Staph. Aureus	H.Infl- uenzae	Colon group bacilli	Neis- seria	Diphth- eroids	Micro cocci
1	62	M	+				+		
2	65	M	+				+		
4	40	M	+		+				
6	43	M	+	+			+		
IO	64	F	+		+		+		
II	24	M.	+	+			+		
I3	55	M	+	+			+		
I7	45	F		+			+		
I8	3I	M		+			+		
20	62	M	+				+		
22	50	M		+			+	+	
25	65	M	+				+		
26	30	M		+			+		
28	55	F	+				+		
30	65	M	+				+		

Table (4) Pattern of organisms initially
cultured (Group II cases).

Case No.	Age "y"	Sex	B.Haem. strept.	Staph aure	H.Infl- uenzae	Colon group bacilli	Neis- seria	Diphth- eroids	Micro- coccus
3	45	F	+				+	+	+
5	19	M	+				+		
7	40	F		+			+		
8	62	M	+				+		
9	55	M				+			
I2	55	M	+	+			+		+
I4	25	F		+			+		
I5	35	M		+				+	
I6	65	M			+		+		
I9	21	M	+	+			+		
21	55	M	+						
23	55	M	+	+			+		
24	25	F		+			+		
27	55	M	+				+		
29	55	M	+				+		

Table (5) shows the frequency of each organism and its percentage for each group separately.

(Frequency and percentage of isolated organisms).

Organisms	Group I		Group II	
	No. of cases	%	No. of cases	%
1. B. Haemolytic strept.	11	73.33	9	60
2. Staph aureus	7	46.66	7	46.66
3. H. influenzae	2	13.33	1	6.66
4. Colon group bacilli	-	0.00	1	6.66
5. Neisseria	14	93.33	12	80.00
6. Diphtheroids	1	6.66	2	13.33
7. Micrococcus	-	0.00	2	13.33

Beta-haemolytic streptococci are still the most frequently isolated pathogenic organism in each treated group. It was isolated in 11 cases (73.33 %) of group I and in 9 cases (60 %) of group II. The frequency of isolation of staph aureus was the same in both groups - 7 cases with a percentage of 46.66 % . Haemophilus influenzae was isolated in 2 cases of group I (13.33 %) and in one case of group II (6.66 %). Colon group bacilli was isolated in one case of group II. Neisseria was so frequent as expected in both groups 14 cases (93.33 %) and 12 cases - (80 %) in group I and group II respectively.

The invitro susceptibility of the organisms initially isolated to both drugs " Lidaprim" and "Septrin" is recorded in table (6) for each case.

Table (6) : The diameter of inhibition zone as measured from the periphery of discs impregnant with "Lidaprim" and "Septrin".

Case No.	" Lidaprim inhibition zone (mm.)	Septrin inhibition Zone (mm.)
1	15	17
2	8	6
3	10	12
4	13	13
5	12	15
6	23	22
7	5	10
8	22	20
9	15	15
10	20	5
11	25	32
12	13	12
13	5	4
14	16	20
15	5	5
16	13	12
17	18	15
18	15	15
19	12	10
20	17	12
21	19	12
22	30	22
23	15	9
24	18	10
25	22	15
26	18	12
27	7	5
28	13	7
29	10	22
30	15	15

Table (7) : The diameter of inhibition zones for different groups of organisms

Organism combination	Case No.	Lidaprim inhibition Zone (mm.)	Septrin inhibition zone (mm.)
B.Haemolytic streptococci + neisseria	1	15	17
	2	8	6
	3	10	12
	5	12	15
	8	22	20
	20	17	12
	25	22	15
	27	7	5
	28	13	7
	29	10	22
	30	15	15
Pure B.Haemolytic Strept.	21	19	12
Staph aureus + Neisseria	7	3	10
	14	16	20
	17	18	15
	18	15	15
	24	18	10
	26	18	12
Staph aureus +diphtheroids	15	5	5
	22	30	22
B.Haemolytic strept.+staph aureus and neisseria	6	23	22
	11	25	32
	12	13	12
	13	5	4
	19	12	10
	23	15	9
H.Influenzae + B.H.Strept.	4	13	13
	10	20	5
H.Influenzae+Neisseria	16	13	12
Colon group bacilli	9	15	15

The degree of invitro susceptibility depends on the diameter of the inhibition zone. The wider the diameter of the inhibition zone the more the susceptibility and vice versa.

The inhibition zones representing the invitro susceptibility to both drugs are illustrated in table (7).

The test was done on group of organism isolated from each patient and not for each organism separately .

- Beta-haemolytic streptococci & neisseria Combination group:

11 cases - 6 of them were more invitro susceptible to Lidaprim than Septrin; one case showed equal invitro susceptibility while the remaining 4 cases were less susceptible to Lidaprim than Septrin.

- Pure B.H.Streptococci : One case and the organism was more Susceptible to Lidaprim than to Septrin .

- Staph. aureus with either neisseria or diphtheroids :

8 cases were illustrated, 4 of them were more susceptible to Lidaprim , 2 cases had equal invitro susceptibility to both drugs and 2 cases were less susceptible to Lidaprim than Septrin .

- B.H.Streptococci, staph aureus & neisseria combination :

6 cases - 5 of them showed more susceptibility to

Lidaprim and the remaining case was less susceptible to Lidaprim than Septrin.

- H.Influenzae and B.Haemolytic streptococci : were detected in 2 cases , one showed equal susceptibility and the other showed higher susceptibility to Lidaprim.

One case with H.Influenzae and neisseria showed more invitro susceptibility to Lidaprim. One case with pure colon group bacilli showed equal susceptibility.

It can be concluded that the invitro susceptibility to lidaprim is more than that to Septrin in various organism combination groups isolated initially in cases with chronic bronchitis.

Table (8) shows the diameter of inhibition zones for each treat of group .

Group I received Lidaprim :

- 10 cases were more invitro susceptible to Lidaprim
- 3 cases showed equal susceptibility to both drugs.
- 2 cases were less susceptible to Lidaprim.

Group II Received Septrin :

- 5 cases were more invitro susceptible to Septrin
- 2 cases showed equal susceptibility
- 8 cases were less susceptible to Septrin.

Table (8) : The diameter of inhibition zones for each treated group.

Group I treated with Lidaprim			Group II treated with Septrin		
Case No.	Lidaprim inhibition zone (mm.)	Septrin inhibition zone (mm.)	Case No.	Lidaprim inhibition zone (mm.)	Septrin inhibition zone (mm.)
I	I5	I7	3	I0	I2
2	8	6	5	I2	I5
4	I3	I3	7	5	I0
6	23	22	8	22	20
I0	20	5	9	I5	I5
II	25	32	I2	I3	I2
I3	5	4	I4	I6	20
I7	I8	I5	I5	5	5
I8	I5	I5	I6	I3	I2
20	I7	I2	I9	I2	I0
22	30	22	2I	I9	I2
25	22	I5	23	I5	9
26	I8	I2	24	I8	I0
28	I3	7	27	7	5
30	I5	I5	29	I0	22

After 10 days treatment with either Lidaprim or Septrin , the patients were assessed bacteriologically, clinically and functionally.

The bacteriological response studied in Group I is illustrated in table (9). All organisms disappeared in 8 cases (53.33 %) - some of the organisms disappeared in 7 cases (46.66 %) and those not disappeared showed invitro susceptibility to both drugs. New organisms did not emerge and no invitro resistance developed.

Table (9): Bacteriological response studied in group

received Lidaprim for 10 days.

Case	All organ- isms dis- appeared	Some orga- nisms dis- appeared	No orga- nisms dis- appeared	Emerg- ing or- ganisms	Sensitivity			
					Initial Lid. I.Z	Sep. I.Z	After treat. Lid. I.Z	Sep. I.Z
					m.m		m.m	
1	+				I5	I7	..	..
2		+			8	6	I0	8
4	+				I3	I3	..	..
6		+			23	22	I8	I5
I0		+			20	5	20	I2
II		+			25	32	20	30
I3		+			5	4	I8	I0
I7		+			I8	I5	I5	I5
I8	+				I5	I5	..	..
20	+				I7	I2	..	..
22		+			30	22	5	5
25	+				22	I5	..	..
26	+				I8	I2	..	..
28	+				I3	7	..	..
30	+				I5	I5	..	..
Total no.of cases	8	7	..	..				
%	53.33%	46.66%	0 %	0 %				

Table (10) : Bacteriological response studied in
group II received Septrin

Case No.	All organisms disappeared	Some organisms disappeared	No organisms disappeared	Emerging organisms	Initial susceptibility		After Treatment susceptibility	
					Lidaprim	Septrin	Lidaprim	Septrin
					I.Z m.m	I.Z m.m	I.Z m.m	I.Z m.m
3	+				I0	I2	..	..
5		+			I2	I5	I2	I6
7	+				5	I0	..	..
8		+			22	20	22	I0
9	+				I5	I5	..	..
I2		+			I3	I2	5	I0
I4		+			I6	20	20	20
I5		+		+	5	5	7	5
I6	+			+	I3	I2	r e s i s t a n t	
I9		+			I2	I0	I0	8
2I	+			+	I9	I2	r e s i s t a n t	
23			+		I5	9	I7	I7
24		+			I8	I0	I0	8
27		+			7	5	8	9
29	+				I0	22	..	..
Total					6	8	I	3
					%	%	%	%
					40 %	53.33 %	6.66 %	20 %

Table (10) illustrates the bacteriological response in patients of group II . All organisms disappeared in 6 cases (40 %) . Some of the organisms disappeared in 8 cases (53.33 %), & those organisms were still susceptible to both drugs. One of these cases "case no.15" was associated with emergence of neisseria which may be missed in the initial culture. None of the organisms disappeared in one case and they were still invitro - susceptible to both drugs. Case no. 16 and 21 showed disappearance of the original organisms with emergence of new ones. The emerged organisms were strept. viridans and they were not susceptible to both drugs. Streptococcus viridans is a usual commensal of the throat and it may have been missed in the first isolation.

Clinical response as assessed for group I and group II were illustrated in tables 11, 12 respectively. It is clear that clinical response of group I is better than that of group II when different clinical parameters are compared separately for each group (table 13).

Table (11) :Clinical response to treatment
"Lidaprim group"

Parameter	Good response		Fair response		Poor response	
	No. of cases	%	No. of cases	%	No. of cases	%
Cough	15	100	..	..	..	..
Temp.	15	100	..	..	..	..
Pulse rate	15	100	..	..	..	..
Respiratory rate	14	93.33	1	6.66	..	..
Rhonchi	14	93.33	1	6.66	..	..
Amount of sputum	15	100	..	..	..	..
Character of sputum	15	100	..	..	..	..

Table(12): Clinical response to treatment
"Septrin group".

Cough	14	93.33	1	6.66	..	..
Temp.	15	100	..	..	..	..
Pulse rate	14	93.33	1	6.66	..	..
Respiratory rate	11	73.33	4	26.66	..	..
Rhonchi	12	80	3	20	..	..
Amount of sputum	12	80	3	20	..	..
Character of sputum	13	86.66	2	13.33	..	..

Table (13): Clinical response to both treatment groups.

Parameter	Good response		Fair response		Poor response	
	Lidaprim	Septirin	Lidaprim	Septirin	Lidaprim	Septirin
	No. of cases	%	No. of cases	%	No. of cases	%
Cough	I5	I00	I4	99.33	..	..
Temp.	I5	I00	I5	I00	..	..
Pulse rate	I5	I00	I4	93.33	..	..
Respiratory rate	I4	93.33	II	73.33	I	6.66
Rhonnehi	I4	93.33	I2	80	I	6.66
Amount of sputum	I5	I00	I2	80	..	..
Character of sputum	I5	I00	I3	86.66	..	..

Table (14) : FEV, before and after 10 days
treatment with Lidaprim.

Case No.	Initial value		Final	
	Absolute value	%	Absolute value	%
1	I.80 L	46.75	I.95 L	50.64
2	0.72 L	I5.58	0.75 L	I6.23
4	0.84 L	23.33	0.72 L	20.00
6	0.45 L	II.84	I.I2 L	29.47
IO	0.60 L	I8.57	0.68 L	20.89
II	I.29 L	35.83	2.I0 L	58.33
I3	0.69 L	I9.I6	0.93 L	25.83
I7	0.99 L	25.00	I.38 L	34.84
I8	I.29 L	26.59	I.74 L	35.87
20	I.80 L	46.75	2.55 L	66.23
22	I.74 L	46.09	I.89 L	48.74
25	I.05 L	25.30	I.84 L	44.33
26	I.37 L	28.24	2.02 L	4I.64
28	0.48 L	I7.I4	0.72 L	25.7I
30	0.75 L	I7.85	0.93 L	22.I4
$\bar{X}$	I.06 L	26.93	I.42 L	36.06
S.D.	0.45		0.60	

N.B. : $\bar{X}$ = Mean value

S.D. = Standard deviation.

All figures mentioned in the following tables are approximated to avoid decimals.

Table (15) : FEV₁ before and after 10 days
treatment with Septrin.

Case No.	Initial value		Final	
	Absolute value	%	Absolute value	%
3	1.80 L	46.75	1.05 L	27.27
5	2.46 L	65.25	2.76 L	73.20
7	1.80 L	46.63	1.68 L	43.52
8	0.57 L	14.54	0.96 L	24.48
9	1.29 L	34.63	1.95 L	52.34
12	0.42 L	10.63	0.54 L	13.67
14	1.23 L	46.24	1.08 L	40.60
15	0.66 L	17.14	0.96 L	24.93
16	0.93 L	22.40	0.90 L	21.68
19	1.23 L	33.24	1.42 L	38.37
21	1.29 L	34.63	1.18 L	31.67
23	0.95 L	24.05	0.84 L	21.13
24	1.29 L	48.49	1.18 L	44.36
27	1.28 L	35.55	1.65 L	45.83
29	0.96 L	24.00	0.87 L	21.75
$\bar{X}$	1.21 L	33.61	1.26 L	34.99
S.D.	0.51		0.54	

Table (16) : FVC before and after 10 days
treatment with Lidaprim

Case	Initial value		Final value	
	Absolute value	%	Absolute value	%
I	2.49 L	64.75	2.91 L	75.5
2	2.01 L	43.45	2.97 L	64.21
4	1.56 L	43.33	1.55 L	42.91
6	1.50 L	41.65	2.02 L	53.15
10	1.14 L	35.29	1.25 L	38.54
11	2.55 L	70.83	3.01 L	83.66
13	2.01 L	55.83	1.38 L	38.33
17	1.65 L	41.66	2.40 L	60.60
18	3.45 L	71.13	3.75 L	77.31
20	2.72 L	70.64	3.12 L	81.03
22	2.82 L	74.7	3.15 L	83.44
25	2.01 L	48.43	2.97 L	67.22
26	3.65 L	75.25	3.95 L	81.44
28	1.68 L	60.00	1.77 L	63.21
30	1.32 L	32.14	1.59 L	37.85
$\bar{X}$	2.17 L	55.27	2.52 L	63.23
S.D.	0.73		0.84	

Table (17) : FVC before and after 10 days
treatment with Septrin.

Case No.	Initial value		Final value	
	Absolute value	%	Absolute value	%
3	2.49 L	64.75	1.77 L	58.00
5	2.70 L	71.61	3.03 L	80.03
7	2.10 L	54.40	2.28 L	59.06
8	1.02 L	26.02	1.29 L	32.90
9.	2.55 L	68.45	2.94 L	78.92
12	0.93 L	23.54	1.89 L	47.84
14	2.43 L	91.35	2.22 L	83.45
15	1.50 L	38.96	1.89 L	49.09
16	1.53 L	36.86	1.56 L	37.59
19	2.13 L	57.56	2.52 L	68.10
21	2.25 L	60.40	2.12 L	56.91
23	1.32 L	33.41	1.89 L	47.84
24	1.85 L	69.54	1.72 L	64.66
27	2.45 L	65.77	2.83 L	75.97
29	2.40 L	60.00	2.34 L	58.50
$\bar{X}$	1.98 L	54.84	2.15 L	59.92
S.D.	0.56		0.50	

Table (18) : MVV before and after treatment with
Lidaprim .

Case No.	Initial		Final	
	Absolute value	%	Absolute value	%
I	60.00 L	75.00	67.00 L	84.00
2	30.00 L	30.61	30.24 L	30.85
4	29.64 L	31.87	32.76 L	35.22
6	19.80 L	20.41	50.60 L	52.16
10	24.00 L	34.78	36.00 L	52.17
11	58.80 L	56.00	86.32 L	82.20
13	31.08 L	38.37	29.16 L	36.00
17	53.76 L	52.70	68.40 L	67.05
18	58.80 L	43.88	59.76 L	44.59
20	66.00 L	82.50	70.13 L	87.66
22	79.56 L	86.47	45.24 L	49.17
25	40.12 L	46.11	51.27 L	58.93
26	58.85 L	43.91	70.47 L	52.58
28	54.00 L	79.41	55.08 L	81.00
30	19.20 L	22.32	36.48 L	42.41
$\bar{X}$	45.75 L	49.62	52.59 L	57.07
S.D.	18.21		16.96	

Table (18) : MVV before and after treatment with Lidoprim .

Case No.	Initial		Final	
	Absolute value	%	Absolute value	%
I	60.00 L	75.00	67.00 L	84.00
2	30.00 L	30.61	30.24 L	30.85
4	29.64 L	31.87	32.76 L	35.22
6	19.80 L	20.41	50.60 L	52.16
10	24.00 L	34.78	36.00 L	52.17
11	58.80 L	56.00	86.32 L	82.20
13	31.08 L	38.37	29.16 L	36.00
17	53.76 L	52.70	68.40 L	67.05
18	58.80 L	43.88	59.76 L	44.59
20	66.00 L	82.50	70.13 L	87.66
22	79.56 L	86.47	45.24 L	49.17
25	40.12 L	46.11	51.27 L	58.93
26	58.85 L	43.91	70.47 L	52.58
28	54.00 L	79.41	55.08 L	81.00
30	19.20 L	22.32	36.48 L	42.41
$\bar{X}$	45.75 L	49.62	52.59 L	57.07
S.D.	18.21		16.96	

Lung function tests performed :

Tables 14 and 15 illustrate the forced expiratory volume in the first second (FEV) at the beginning and end of each treatment period. It was expressed in litres and as a percentage to the predicted vital capacity of the patient. Tables 16 and 17 show the values of vital capacity for each group at the beginning and end of treatment. Tables 18 , 19 illustrate the ~~maximum~~ voluntary ventilation (MVV) before and after treatment with Lidaprim and Septrin respectively

The average value of FEV , VC , MVV were much reduced prior to treatment below normal predicted values. Nearly the same rate of reduction persisted after administration of "Lidaprim"(group I) or "Septrin"(group II) inspite of the presence of minimal increase which seemed insignificant.

Both "Lidaprim" and "Septrin" tolerability were high. No side effects have been clinically detected all through the study.

The serum creatinine level showed no rise above normal levels (0.5 - 1.5 mg /100 ml) except in 2 cases received Lidaprim (13.3 %) and 2 cases (13.3 %) received Septrin (Table 20). Also the serum glutamic pyruvic transaminase level did not show rise above normal levels (5-35 Unit/ml)

except in one case received Lidaprim (6.7 %) which the initial level was higher than normal (Table 21).

There was no significant difference after treatment with either "Lidaprim" or "Septrin" in the haemoglobin, white cell count, polymorph count or platelet count.

Total urine analysis after 10 days treatment with either "Lidaprim" or "Septrin" showed no significant changes.

Table (20) Serum creatinine levels before and after
10 days treatment.

Group I			Group II		
Case	Initial	Final	Case	Initial	Final
3	0.9	1.2	I	0.9	2.0 mg %
5	1.4	1.5	2	0.9	0.9
7	1.2	1.1	4	1.6	0.9
8	1.1	2.2	6	0.9	1.5
9	1.5	1.5	10	1.5	1.4
12	0.9	1.1	11	1.5	1.5
14	1.1	1.8	13	1.2	1.3
15	0.1	1.2	17	1.2	1.5
16	1.1	1.5	18	1.0	1.0
19	1.2	1.4	20	0.9	1.1
21	1.2	1.5	22	1.8	1.1
23	0.8	1.2	25	0.9	0.8
24	1.1	1.3	26	1.0	1.1
27	1.5	1.5	28	1.2	1.7
29	0.6	0.8	30	1.1	1.4
$\bar{X}$	1.05	1.39	$\bar{X}$	1.17	1.28
S.D	0.35	0.32	S.D	0.29	0.32

Table (21) : Serum glutamic pyruvic transaminase(SGPT)
level before and after 10 days treatment.
(Unit/ml.)

Group I			Group II		
Case No.	Initial	Final	Case No.	Initial	Final
I	6	I3	3	9	I5
2	22	II	5	25	3I
4	37	74	7	9	9
6	9	34	8	23	30
IO	7	25	9	4	3
II	5	I5	I2	20	23
I3	4	7	I4	I3	20
I7	II	25	I5	6	6
I8	I7	I5	I6	5	4
20	6	5	I9	I2	IO
22	20	II	2I	.8	IO
25	IO	I2	23	8	6
26	IO	8	24	I3	I5
28	II	I8	27	5	6
30	8	6	29	II	I2
$\bar{X}$	I2.07	I8.6	$\bar{X}$	II .4	I3.33
S.D	8.26	I6.72	S.D	6.32	8.68