

Statistical Calculations of the Confidence Interval and Significant Difference Ranges of the Morphologic Index¹

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Since Hansen first noted variations in the morphology of leprosy bacilli in 1895, many investigators have given attention to such morphologic variations as revealed by stained preparations. After the advent of antileprosy drugs, many clinicians observed rapid decrease in the proportion of uniformly stained bacilli under therapy. In 1960 Ridley first proposed a "Granularity Index" based on three forms of the bacilli (solid, fragmented and granular) for quantitative assessment of these morphologic changes (⁴). As the granularity index was too complex to be readily used clinically, the "Morphologic Index" (MI) based on two forms of the organisms, solid and non-solid, was proposed a few years later.

Since leprosy bacilli are, as yet, uncultivable *in vitro*, it is still useful to follow the morphologic changes in leprosy bacilli during the course of chemotherapy. The MI is thus widely used, not only in clinical practice, but also in laboratory experiments. However, many basic problems regarding the MI remain unsolved. Thus satisfactory studies on the statistical basis of the MI are not yet available. This report is an attempt to study some statistical properties of the MI as it is usually carried out from a direct smear.

Morphologic Index and binomial distribution. Even in a small lepromatous lesion there is a huge set of leprosy bacilli which consists of numerous solid bacilli and numerous non-solid bacilli. The ratio of the solid bacilli to the total bacilli in the lesion is the Morphologic Index of this bacillary set, or, in statistical term, the MI of the "Population." Although we are seeking to know the real value of MI, it is impossible to know the exact value of the MI of

whole bacillary population of the lesion or of the patient. In the strict sense of the word, the MI is not the MI of the lesion but the MI of the sample. The task, then, is to infer the real value of MI of the lesion from the MI of the sample. For this purpose, statistical theory and methods of sampling should be used.

In the examination of MI, all leprosy bacilli are divided into two classes (solid and non-solid), based on morphologic characteristics in staining. In statistics, this type of population is termed a binomial population and the sample ratio from this type of population has the "Binomial Distribution."

Theoretical considerations. The larger the number of bacilli that one examines in calculating the MI, the more closely one will estimate the true MI in the patient. The practical limitations of technician time and of visual fatigue (which gives to increasing inaccuracy) usually limit the count to 100, 200 or 400 bacilli. Although 1000 bacilli may occasionally be counted, it must be remembered that the gain in reliability does not increase directly with the number of bacilli counted (⁶). Thus the relative gain in the accuracy of one's estimate that comes from counting 200 rather than 100 bacilli is greater than the gain in accuracy in going from 400 to 1000 bacilli. For this reason, the tables presented below for the convenience of the person trying to estimate the 95% confidence interval (the range within which the true MI of the patient has a 95% probability of lying) from doing a single MI count are arranged to provide the user with an easily-found confidence interval with any solid count found by counting 100, 200, or 400 bacilli. For the mathematical theory and computational methods that gave rise to this practical and convenient table, one should refer to any standard statistical text, such as Mood and Graybill (²).

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RESULTS

If 400 bacilli are counted in a smear and the number of solid bacilli is 80, then the MI is completed at 20%. The real MI of the leprosy lesion from which the specimen is taken lies in the range of from 16.49% to 23.84% with 95% reliability.

Number of Solid Bacilli	MI (%)	Confidence Intervals
80	20.00	16.49-23.84

The calculated confidence intervals of the MI when 100 bacilli are counted is presented in Table 1, for 200 bacilli in Table 2, and for 400 bacilli in Table 3.

Testing significant differences between two Morphologic Indices. In practical use of the MI, it is often necessary to compare the values of the MI of two patients or the MI of two different samples from the same patient taken at different times during treatment. In this comparison, though a small difference is found between them, we will not regard it as "significant" immediately because it is recognized that the MI of a sample always is associated with sample variation. In order to know accurately whether a difference between two MI is "significant" or not, statistical determination must be performed. The most common method of the "Fourfold Contingency Table" can be used (3).

Let us suppose there are two samples of size N named Sample A and Sample B. The number of solid bacilli in Sample A is r and that of Sample B is x . For the convenience of the test, they are tabulated in the following table. This type of table is called a "Fourfold Contingency Table."

	Solid bacilli	Non-solid bacilli	Total
Sample A	r	$N-r$	N
Sample B	x	$N-x$	N
Total	$r+x$	$2N-r-x$	$2N$

Then, the chi-square value is computed. That is

$$\chi^2 = \frac{\{r(N-x)-x(N-r)\} 2 \times 2N}{N : N \cdot (r+x) (2N-r-x)} = \frac{2N (r-x)^2}{(r+x) (2N-r-x)}$$

If the value of the chi-square thus computed is larger than 3.841, we can state that there is a statistically significant difference between r and x with 95% reliability. So, if an inequality

$$\chi^2 = \frac{2N (r-x)^2}{(r+x) (2N-r-x)} \geq 3.841$$

is solved for x , and actual values are substituted into r , the significant difference ranges of x can be calculated. At the time of using the fourfold contingency table for testing significant difference between two sample ratios, if the values of r or x are near or below 5, then refer to a statistical text for the possible need of using "Yates' correction" for small numbers (needed if the expected number falls below 5 in any cell in the table).

One can sometimes avoid doing the chi-square computation. If the confidence limit for MI count A (as determined from Table 1) does not overlap with the confidence interval for MI count B (as determined from Table 1), then one can be confident (with less than 5% chance of error) that MI count A is different from MI count B. However, if the confidence limits for the two counts do, in fact, overlap each other, then one must go ahead and perform the chi-square test as described above.

DISCUSSION

For the application of statistical methods or theories about sampling to clinical practice or laboratory experiments, it is required that a sample is a "Random Sample." So, if a random sample cannot be made easily, the clinical application of MI becomes very difficult. Therefore, in order to see whether the widely used direct smear method can be used for the examination of MI or not, 66 smears were taken from various leprosy lesions of which the Bacterial Indices were from 2 to 6. To examine bacilli in each smear, 100 bacilli were checked in each of the four quadrants of the smear spot. In low-BI smears, the total number of bacilli in each quadrant was examined morphologically. Then, using

TABLE 1. *Confidence intervals of Morphologic Index (counted bacilli: 100).*

Number of solid bacilli (M.I.)	Confidence intervals	Number of solid bacilli (M.I.)	Confidence intervals
0	0.00- 3.62	40	30.35-50.24
1	0.03- 5.45	41	31.28-51.25
2	0.24- 7.04	42	32.22-52.25
3	0.62- 8.52	43	33.16-53.25
4	1.10- 9.93	44	34.10-54.25
5	1.64-11.29	45	35.05-55.24
6	2.23-12.60	46	36.01-56.23
7	2.86-14.01	47	36.97-57.21
8	3.52-15.15	48	37.93-58.19
9	4.20-16.40	49	38.89-59.17
10	4.90-17.62	50	39.86-60.14
11	5.62-18.83	51	40.83-61.11
12	6.36-20.02	52	41.81-62.07
13	7.11-21.20	53	42.79-63.03
14	7.87-22.37	54	43.77-63.99
15	8.65-23.52	55	44.76-64.95
16	9.43-24.67	56	45.75-65.90
17	10.23-25.81	57	46.75-66.84
18	11.04-26.94	58	47.75-67.78
19	11.85-28.07	59	48.75-68.72
20	12.67-29.17	60	49.76-69.65
21	13.43-30.27	61	50.77-70.58
22	14.28-31.37	62	51.79-71.50
23	15.13-32.46	63	52.80-72.42
24	15.99-33.55	64	53.83-73.34
25	16.85-34.63	65	54.85-74.25
26	17.73-35.71	66	55.88-75.16
27	18.60-36.78	67	56.92-76.06
28	19.48-37.85	68	57.95-76.96
29	20.36-38.92	69	58.99-77.86
30	21.25-39.97	70	60.03-78.75
31	22.14-41.01	71	61.08-79.64
32	23.04-42.05	72	62.15-80.52
33	23.94-43.08	73	63.22-81.40
34	24.84-44.12	74	64.29-82.27
35	25.75-45.15	75	65.37-83.15
36	26.66-46.17	76	66.45-84.01
37	27.58-47.20	77	67.54-84.87
38	28.50-48.21	78	68.63-85.72
39	29.42-49.23	79	69.73-86.57

TABLE 1. *Continued*

Number of solid bacilli (M.I.)	Confidence intervals	Number of solid bacilli (M.I.)	Confidence intervals
80	70.83-87.33	90	82.38-95.10
81	71.93-88.15	91	83.60-95.80
82	73.06-88.96	92	84.85-96.48
83	74.19-89.77	93	85.99-97.14
84	75.33-90.57	94	87.40-97.77
85	76.48-91.35	95	88.71-98.36
86	77.63-92.13	96	90.07-98.90
87	78.80-92.89	97	91.48-99.38
88	79.98-93.64	98	92.96-99.76
89	81.17-94.38	99	94.55-99.97
		100	96.38-100.0

TABLE 2. *Confidence intervals of Morphologic Index (counted bacilli: 200).*

Number of solid bacilli	M.I.	Confidence intervals	Number of solid bacilli	M.I.	Confidence intervals
0	0.0	0.00- 1.83	30	15.0	10.37-20.70
1	0.5	0.01- 2.75	31	15.5	10.80-21.24
2	1.0	0.12- 3.57	32	16.0	11.23-21.79
3	1.5	0.31- 4.32	33	16.5	11.66-22.34
4	2.0	0.55- 5.04	34	17.0	12.10-22.89
5	2.5	0.82- 5.74	35	17.5	12.53-23.43
6	3.0	1.11- 6.41	36	18.0	12.97-23.98
7	3.5	1.42- 7.09	37	18.5	13.14-24.52
8	4.0	1.74- 7.73	38	19.0	13.85-25.06
9	4.5	2.08- 8.37	39	19.5	14.29-25.61
10	5.0	2.42- 9.00	40	20.0	14.74-26.15
11	5.5	2.78- 9.63	41	20.5	15.18-26.69
12	6.0	3.14-10.24	42	21.0	15.63-27.23
13	6.5	3.51-10.86	43	21.5	16.07-27.77
14	7.0	3.88-11.47	44	22.0	16.52-28.31
15	7.5	4.26-12.06	45	22.5	16.97-28.84
16	8.0	4.64-12.66	46	23.0	17.42-29.38
17	8.5	5.03-13.25	47	23.5	17.87-29.92
18	9.0	5.43-13.84	48	24.0	18.32-30.45
19	9.5	5.82-14.44	49	24.5	18.77-30.99
20	10.0	6.22-15.01	50	25.0	19.22-31.52
21	10.5	6.62-15.59	51	25.5	19.68-32.05
22	11.0	7.03-16.16	52	26.0	20.13-32.58
23	11.5	7.44-16.73	53	26.5	20.59-33.11
24	12.0	7.85-17.30	54	27.0	21.04-33.64
25	12.5	8.27-17.87	55	27.5	21.50-34.17
26	13.0	8.68-18.44	56	28.0	21.96-34.70
27	13.5	9.10-19.01	57	28.5	22.42-35.23
28	14.0	9.52-19.58	58	29.0	22.88-35.76
29	14.5	9.94-20.15	59	29.5	23.34-36.29

TABLE 2. *Continued*

Number of solid bacilli	M.I.	Confidence intervals	Number of solid bacilli	M.I.	Confidence intervals
60	30.0	23.80-36.78	110	55.0	48.30-61.58
61	30.5	24.28-37.28	111	55.5	48.80-62.07
62	31.0	24.76-37.78	112	56.0	49.29-62.56
63	31.5	25.25-38.28	113	56.5	49.79-63.05
64	32.0	25.73-38.78	114	57.0	50.29-63.54
65	32.5	26.21-39.27	115	57.5	50.78-64.03
66	33.0	26.70-39.77	116	58.0	51.28-64.52
67	33.5	27.18-40.27	117	58.5	51.77-65.01
68	34.0	27.67-40.77	118	59.0	52.27-65.51
69	34.5	28.15-41.27	119	59.5	52.77-66.00
70	35.0	28.64-41.76	120	60.0	53.26-66.48
71	35.5	29.12-42.26	121	60.5	53.76-66.97
72	36.0	29.61-42.76	122	61.0	54.26-67.46
73	36.5	30.10-43.26	123	61.5	54.75-67.95
74	37.0	30.58-43.75	124	62.0	55.25-68.44
75	37.5	31.07-44.25	125	62.5	55.75-68.93
76	38.0	31.56-44.75	126	63.0	56.25-69.42
77	38.5	32.05-45.25	127	63.5	56.74-69.90
78	39.0	32.54-45.74	128	64.0	57.24-70.39
79	39.5	33.03-46.24	129	64.5	57.74-70.88
80	40.0	33.52-46.74	130	65.0	58.24-71.36
81	40.5	34.00-47.23	131	65.5	58.73-71.85
82	41.0	34.49-47.73	132	66.0	59.23-72.33
83	41.5	34.99-48.23	133	66.5	59.73-72.82
84	42.0	35.48-48.72	134	67.0	60.23-73.30
85	42.5	35.97-49.22	135	67.5	60.73-73.79
86	43.0	36.46-49.71	136	68.0	61.22-74.27
87	43.5	36.95-50.21	137	68.5	61.72-74.75
88	44.0	37.44-50.71	138	69.0	62.22-75.24
89	44.5	37.93-51.20	139	69.5	62.72-75.72
90	45.0	38.42-51.70	140	70.0	63.22-76.20
91	45.5	38.92-52.19	141	70.5	63.71-76.66
92	46.0	39.41-52.69	142	71.0	64.24-77.12
93	46.5	39.90-53.18	143	71.5	64.77-77.58
94	47.0	40.39-53.68	144	72.0	65.30-78.04
95	47.5	40.89-54.17	145	72.5	65.83-78.50
96	48.0	41.38-54.67	146	73.0	66.36-78.96
97	48.5	41.87-55.16	147	73.5	66.89-79.41
98	49.0	42.37-55.66	148	74.0	67.42-79.87
99	49.5	42.86-56.15	149	74.5	67.95-80.32
100	50.0	43.35-56.65	150	75.0	68.48-80.78
101	50.5	43.85-57.14	151	75.5	69.01-81.23
102	51.0	44.34-57.63	152	76.0	69.55-81.68
103	51.5	44.84-58.13	153	76.5	70.08-82.13
104	52.0	45.33-58.62	154	77.0	70.62-82.58
105	52.5	45.83-59.11	155	77.5	71.16-83.03
106	53.0	46.32-59.61	156	78.0	71.69-83.48
107	53.5	46.82-60.10	157	78.5	72.23-83.93
108	54.0	47.31-60.59	158	79.0	72.77-84.37
109	54.5	47.81-61.08	159	79.5	73.31-84.82

TABLE 2. *Continued*

Number of solid bacilli	M.I.	Confidence intervals	Number of solid bacilli	M.I.	Confidence intervals
160	80.0	73.85-85.26	180	90.0	84.99-93.78
161	80.5	74.39-85.71	181	90.5	85.56-94.18
162	81.0	74.94-86.15	182	91.0	86.16-94.58
163	81.5	75.48-86.59	183	91.5	86.75-94.97
164	82.0	76.02-87.03	184	92.0	87.34-95.36
165	82.5	76.57-87.47	185	92.5	87.94-95.74
166	83.0	77.11-87.90	186	93.0	88.53-96.12
167	83.5	77.66-88.34	187	93.5	89.14-96.49
168	84.0	78.21-88.77	188	94.0	89.76-96.86
169	84.5	78.76-89.20	189	94.5	90.37-97.22
170	85.0	79.30-89.63	190	95.0	91.00-97.58
171	85.5	79.85-90.06	191	95.5	91.63-97.92
172	86.0	80.42-90.48	192	96.0	92.27-98.26
173	86.5	80.99-90.90	193	96.5	92.91-98.58
174	87.0	81.56-91.32	194	97.0	93.59-98.89
175	87.5	82.13-91.73	195	97.5	94.26-99.18
176	88.0	82.70-92.15	196	98.0	94.96-99.45
177	88.5	83.27-92.56	197	98.5	95.68-99.69
178	89.0	83.84-92.97	198	99.0	96.43-99.88
179	89.5	84.41-93.38	199	99.5	97.25-99.99
			200	100.0	98.17-100.0

TABLE 3. Confidence intervals of Morphologic Index (counted bacilli: 400).

Number of solid bacilli	M.I. (%)	Confidence intervals	Number of solid bacilli	M.I. (%)	Confidence intervals
0	0.00	0.00- 0.92	20	5.00	3.08- 7.61
1	0.25	0.01- 1.40	21	5.25	3.28- 7.90
2	0.50	0.06- 1.79	22	5.50	3.48- 8.20
3	0.75	0.15- 2.18	23	5.75	3.68- 8.49
4	1.00	0.27- 2.54	24	6.00	3.89- 8.78
5	1.25	0.41- 2.89	25	6.25	4.09- 9.08
6	1.50	0.55- 3.23	26	6.50	4.29- 9.37
7	1.75	0.71- 3.57	27	6.75	4.50- 9.66
8	2.00	0.87- 3.90	28	7.00	4.71- 9.95
9	2.25	1.03- 4.23	29	7.25	4.91-10.24
10	2.50	1.21- 4.55	30	7.50	5.12-10.52
11	2.75	1.38- 4.87	31	7.75	5.33-10.80
12	3.00	1.56- 5.18	32	8.00	5.54-11.09
13	3.25	1.74- 5.49	33	8.25	5.76-11.37
14	3.50	1.93- 5.80	34	8.50	5.97-11.65
15	3.75	2.11- 6.11	35	8.75	6.19-11.93
16	4.00	2.30- 6.41	36	9.00	6.40-12.21
17	4.25	2.50- 6.71	37	9.25	6.62-12.49
18	4.50	2.69- 7.02	38	9.50	6.83-12.76
19	4.75	2.89- 7.32	39	9.75	7.05-13.04

TABLE 3. *Continued*

Number of solid bacilli	M.I. (%)	Confidence intervals	Number of solid bacilli	M.I. (%)	Confidence intervals
40	10.00	7.26-13.32	90	22.50	18.92-26.34
41	10.25	7.48-13.60	91	22.75	19.17-26.59
42	10.50	7.70-13.88	92	23.00	19.41-26.84
43	10.75	7.92-14.16	93	23.25	19.66-27.09
44	11.00	8.13-14.44	94	23.50	19.90-27.34
45	11.25	8.35-14.71	95	23.75	20.15-27.60
46	11.50	8.57-14.99	96	24.00	20.39-27.85
47	11.75	8.79-15.27	97	24.25	20.64-28.10
48	12.00	9.01-15.55	98	24.50	20.88-28.35
49	12.25	9.23-15.82	99	24.75	21.13-28.60
50	12.50	9.45-16.10	100	25.00	21.37-28.85
51	12.75	9.67-16.38	101	25.25	21.62-29.10
52	13.00	9.89-16.65	102	25.50	21.86-29.35
53	13.25	10.11-16.93	103	25.75	22.11-29.60
54	13.50	10.33-17.21	104	26.00	22.35-29.85
55	13.75	10.56-17.48	105	26.25	22.60-30.10
56	14.00	10.78-17.76	106	26.50	22.85-30.35
57	14.25	11.00-18.03	107	26.75	23.09-30.60
58	14.50	11.22-18.31	108	27.00	23.34-30.85
59	14.75	11.45-18.58	109	27.25	23.58-31.10
60	15.00	11.67-18.83	110	27.50	23.83-31.35
61	15.25	11.91-19.09	111	27.75	24.08-31.60
63	15.50	12.15-19.34	112	28.00	24.32-31.85
63	15.75	12.39-19.59	113	28.25	24.57-32.10
64	16.00	12.62-19.84	114	28.50	24.82-32.35
65	16.25	12.86-20.09	115	28.75	25.06-32.60
66	16.50	13.10-20.34	116	29.00	25.31-32.85
67	16.75	13.34-20.59	117	29.25	25.56-33.10
68	17.00	13.58-20.84	118	29.50	25.80-33.35
69	17.25	13.83-21.09	119	29.75	26.05-33.60
70	17.50	14.07-21.34	120	30.00	26.30-33.85
71	17.75	14.31-21.59	121	30.25	26.54-34.10
72	18.00	14.55-21.84	122	30.50	26.79-34.35
73	18.25	14.79-22.09	123	30.75	27.04-34.60
74	18.50	15.03-22.34	124	31.00	27.28-34.85
75	18.75	15.27-22.59	125	31.25	27.53-35.10
76	19.00	15.52-22.84	126	31.50	27.78-35.35
77	19.25	15.76-23.09	127	31.75	28.03-35.60
78	19.50	16.00-23.34	128	32.00	28.27-35.85
79	19.75	16.24-23.59	129	32.25	28.52-36.10
80	20.00	16.49-23.84	130	32.50	28.77-36.35
81	20.25	16.73-24.09	131	32.75	29.02-36.60
82	20.50	16.97-24.34	132	33.00	29.26-36.85
83	20.75	17.22-24.59	133	33.25	29.51-37.10
84	21.00	17.46-24.84	134	33.50	29.76-37.35
85	21.25	17.70-25.09	135	33.75	30.01-37.60
86	21.50	17.95-25.34	136	34.00	30.25-37.85
87	21.75	18.19-25.59	137	34.25	30.50-38.10
88	22.00	18.43-25.84	138	34.50	30.75-38.35
89	22.25	18.68-26.09	139	34.75	31.00-38.60

TABLE 3. *Continued*

Number of solid bacilli	M.I. (%)	Confidence intervals	Number of solid bacilli	M.I. (%)	Confidence intervals
140	35.00	31.25-38.85	190	47.50	43.68-51.34
141	35.25	31.49-39.10	191	47.75	43.93-51.59
142	35.50	31.74-39.35	192	48.00	44.17-51.84
143	35.75	31.99-39.60	193	48.25	44.42-52.09
144	36.00	32.24-39.85	194	48.50	44.67-52.33
145	36.25	32.49-40.10	195	48.75	44.92-52.58
146	36.50	32.73-40.35	196	49.00	45.17-52.83
147	36.75	32.98-40.60	197	49.25	45.42-53.08
148	37.00	33.23-40.85	198	49.50	45.67-53.33
149	37.25	33.48-41.10	199	49.75	45.92-53.58
150	37.50	33.73-41.35	200	50.00	46.17-53.83
151	37.75	33.97-41.60	201	50.25	46.42-54.08
152	38.00	34.22-41.85	202	50.50	46.67-53.33
153	38.25	34.47-42.10	203	50.75	46.92-54.58
154	38.50	34.72-42.35	204	51.00	47.17-54.83
155	38.75	34.97-42.60	205	51.25	47.42-55.08
156	39.00	35.22-42.85	206	51.50	47.67-55.33
157	39.25	35.46-43.10	207	51.75	47.91-55.58
158	39.50	35.71-43.35	208	52.00	48.16-55.83
159	39.75	35.96-43.60	209	52.25	48.41-56.07
160	40.00	36.21-43.85	210	52.50	48.66-56.32
161	40.25	36.46-44.10	211	52.75	48.91-56.57
162	40.50	36.71-44.35	212	53.00	49.16-56.82
163	40.75	36.96-44.60	213	53.25	49.41-57.07
164	41.00	37.20-44.85	214	53.50	49.66-57.32
165	41.25	37.45-45.10	215	53.75	49.91-57.57
166	41.50	37.70-45.35	216	54.00	50.16-57.82
167	41.75	37.95-45.60	217	54.25	50.41-58.07
168	42.00	38.20-45.85	218	54.50	50.66-58.32
169	42.25	38.45-46.10	219	54.75	50.91-58.57
170	42.50	38.70-46.34	220	55.00	51.16-58.81
171	42.75	38.95-46.59	221	55.25	51.41-59.06
172	43.00	39.19-46.84	222	55.50	51.66-59.31
173	43.25	39.44-47.09	223	55.75	51.91-59.56
174	43.50	39.69-47.34	224	56.00	52.16-59.81
175	43.75	39.94-47.59	225	56.25	52.41-60.06
176	44.00	40.19-47.84	226	56.50	52.66-60.31
177	44.25	40.44-48.09	227	56.75	52.91-60.56
178	44.50	40.69-48.34	228	57.00	53.16-60.81
179	44.75	40.94-48.59	229	57.25	53.41-61.05
180	45.00	41.19-48.84	230	57.50	53.66-61.30
181	45.25	41.43-49.09	231	57.75	53.90-61.55
182	45.50	41.68-49.34	232	58.00	54.15-61.80
183	45.75	41.93-49.59	233	58.25	54.40-62.05
184	46.00	42.18-49.84	234	58.50	54.65-62.30
185	46.25	42.43-50.09	235	58.75	54.90-62.55
186	46.50	42.68-50.34	236	59.00	55.15-62.80
187	46.75	42.93-50.59	237	59.25	55.40-63.04
188	47.00	43.18-50.84	238	59.50	55.65-63.29
189	47.25	43.43-51.09	239	59.75	55.90-63.54

TABLE 3. *Continued*

Number of solid bacilli	M.I. (%)	Confidence intervals	Number of solid bacilli	M.I. (%)	Confidence intervals
240	60.00	56.15-63.79	290	72.50	68.65-76.17
241	60.25	56.40-64.04	291	72.75	68.90-76.42
242	60.50	56.65-64.29	292	73.00	69.15-76.66
243	60.75	56.90-64.54	293	73.25	69.40-76.91
244	61.00	57.15-64.78	294	73.50	69.65-77.15
245	61.25	57.40-65.03	295	73.75	69.90-77.40
246	61.50	57.65-65.28	296	74.00	70.15-77.65
247	61.75	57.90-65.53	297	74.25	70.40-77.89
248	62.00	58.15-65.78	298	74.50	70.65-78.14
249	62.25	58.40-66.03	299	74.75	70.90-78.38
250	62.50	58.65-66.27	300	75.00	71.15-78.63
251	62.75	58.90-66.52	301	75.25	71.40-78.87
252	63.00	59.15-66.77	302	75.50	71.65-79.12
253	63.25	59.40-67.02	303	75.75	71.90-79.36
254	63.50	59.65-67.27	304	76.00	72.15-79.61
255	63.75	59.90-67.51	305	76.25	72.41-79.85
256	64.00	60.15-67.76	306	76.50	72.66-80.10
257	64.25	60.40-68.01	307	76.75	72.91-80.34
258	64.50	60.65-68.26	308	77.00	73.16-80.59
259	64.75	60.90-68.51	309	77.25	73.41-80.83
260	65.00	61.15-68.75	310	77.50	73.66-81.08
261	65.25	61.40-69.00	311	77.75	73.91-81.32
262	65.50	61.65-69.25	312	78.00	74.16-81.57
263	65.75	61.90-69.50	313	78.25	74.41-81.81
264	66.00	62.15-69.75	314	78.50	74.66-82.05
265	66.25	62.40-69.99	315	78.75	74.91-82.30
266	66.50	62.65-70.24	316	79.00	75.16-82.54
267	66.75	62.90-70.49	317	79.25	75.41-82.78
268	67.00	63.15-70.74	318	79.50	75.66-83.03
269	67.25	63.40-70.98	319	79.75	75.91-83.27
270	67.50	63.65-71.23	320	80.00	76.16-83.51
271	67.75	63.90-71.48	321	80.25	76.41-83.76
272	68.00	64.15-71.73	322	80.50	76.66-84.00
273	68.25	64.40-71.97	323	80.75	76.91-84.24
274	68.50	64.65-72.22	324	81.00	77.16-84.48
275	68.75	64.90-72.47	325	81.25	77.41-84.73
276	69.00	65.15-72.72	326	81.50	77.66-84.97
277	69.25	65.40-72.96	327	81.75	77.91-85.21
278	69.50	65.65-73.21	328	82.00	78.16-85.45
279	69.75	65.90-73.46	329	82.25	78.41-85.69
280	70.00	66.15-73.70	330	82.50	78.66-85.93
281	70.25	66.40-73.95	331	82.75	78.91-86.17
282	70.50	66.65-74.20	332	83.00	79.16-86.42
283	70.75	66.90-74.44	333	83.25	79.41-86.66
284	71.00	67.15-74.69	334	83.50	79.66-86.90
285	71.25	67.40-74.94	335	83.75	79.91-87.14
286	71.50	67.65-75.18	336	84.00	80.16-87.38
287	71.75	67.90-75.43	337	84.25	80.41-87.61
288	72.00	68.15-75.68	338	84.50	80.66-87.85
289	72.25	68.40-75.92	339	84.75	80.91-88.09

TABLE 3. *Continued*

Number of solid bacilli	M.I. (%)	Confidence intervals	Number of solid bacilli	M.I. (%)	Confidence intervals
340	85.00	81.17-88.33	370	92.50	89.48-94.88
341	85.25	81.42-88.55	371	92.75	89.76-95.09
342	85.50	81.69-88.78	372	93.00	90.05-95.29
343	85.75	81.97-89.00	373	93.25	90.34-95.50
344	86.00	82.24-89.22	374	93.50	90.63-95.71
345	86.25	82.52-89.44	375	93.75	90.92-95.91
346	86.50	82.79-89.67	376	94.00	91.22-96.11
347	86.75	83.07-89.89	377	94.25	91.51-96.32
348	87.00	83.35-90.11	378	94.50	91.80-96.52
349	87.25	83.62-90.33	379	94.75	92.10-96.72
350	87.50	83.90-90.55	380	95.00	92.39-96.92
351	87.75	84.18-90.77	381	95.25	92.68-97.11
352	88.00	84.45-90.99	382	95.50	92.98-97.31
353	88.25	84.73-91.21	383	95.75	93.29-97.50
354	88.50	85.01-91.43	384	96.00	93.59-97.70
355	88.75	85.29-91.65	385	96.25	93.89-97.89
356	89.00	85.56-91.87	386	96.50	94.20-98.07
357	89.25	85.84-92.08	387	96.75	94.51-98.26
358	89.50	86.12-92.30	388	97.00	94.82-98.44
359	89.75	86.40-92.52	389	97.25	95.13-98.62
360	90.00	86.68-92.74	390	97.50	95.45-98.79
361	90.25	86.96-92.95	391	97.75	95.77-98.97
362	90.50	87.24-93.17	392	98.00	96.10-99.13
363	90.75	87.51-93.38	393	98.25	96.43-99.29
364	91.00	87.79-93.60	394	98.50	96.77-99.45
365	91.25	88.07-93.81	395	98.75	97.11-99.59
366	91.50	88.35-94.03	396	99.00	97.46-99.73
367	91.75	88.63-94.24	397	99.25	97.82-99.85
368	92.00	88.91-94.46	398	99.50	98.21-99.94
369	92.25	89.20-94.67	399	99.75	98.60-99.99
			400	100.0	99.08-100.0

the "2x4 contingency table," the homogeneity of MI were tested. It was found that, in 64 smears (96.7%), there were no significant differences between the MI of four quadrants, and in two smears, some significant differences were present between the MI of the four quadrants. As our reliability of the test was 95%, we concluded that the usual direct smear method may be reasonably uniform for the distribution of solid and non-solid bacilli. This means that the most simple direct-smear-method can be used for examination of MI. (These data were presented by Drs. Obara and Izumi, at the 43rd General Meeting of

Japanese Leprosy Association in April 1970.)

Based on this experiment, we have found that the above-mentioned statistical considerations concerning the MI can be used in the clinical practice of leprosy. However, the biological meaning of the morphological changes of leprosy bacilli in stained preparation are not so clear. For the elucidation of this problem, one should refer to the work of Shepard (5) and his colleagues who have done mouse foot-pad inoculations at monthly intervals from patients during the early period of treatment when the MI is falling rapidly. The study done

by Worth (7) to show the loss of infectivity of lepromatous patients with a positive BI may also have some relevance to the biological relevance of a low MI. The statistical consideration of MI can give mathematical basis to these biological experiments and clinical observations.

SUMMARY

Through statistical approaches to the examination of the Morphologic Index (MI), it becomes evident that the examination of MI is a sampling survey of binominal population.

The confidence intervals of MI were calculated by using the mathematically accurate relation between the partial sum of binomial distribution and F-distribution (1, 3). The computed confidence intervals for $N = 100$, 200 and 400 are tabulated in Table 1, 2 and 3.

The statistical meaning of testing significant difference between two MI by means of fourfold contingency table and chi-squared test are discussed.

Based on the results of examination of 66 smears, it is found that the widely used direct-smear-method for BI can also be used for the examination of the MI.

RESUMEN

A través enfoque estadístico del examen del Indice Morfológico (I.M.) se alcaró que el examen del I.M. es un estudio de muestreo de población binomial.

Basándose en la estadística, se calcularon los intervalos de confianza del I.M., utilizando la relación, matemáticamente exacta entre la suma parcial de la distribución binomial y la distribución F (1,3). En las Tablas 1, 2 y 3 se tabulan los intervalos de confianza computados para $N = 100$, 200 y 400 .

Se discute el significado estadístico de comparar diferencias significativas entre dos I.M. por medio de la tabla cuadruple de contingencia y la prueba de chi-cuadrado.

En base al examen de 66 láminas, se encontró que el método ampliamente usado de extendido, que se utiliza para el I.B., puede también utilizarse para el examen del I.M.

RÉSUMÉ

Grâce à un mode d'approche statistique visant à étudier l'Index Morphologique (I.M.) on a clarifié le fait que l'examen par l'Index Morphologique correspond à un sondage par échantillonnage dans une population binomiale.

Basés sur les données statistiques, les intervalles de confiance de l'Index Morphologique ont été calculés en utilisant la relation mathématique adéquate entre la somme partielle de la distribution binomiale et la distribution de F. Les intervalles de confiance ainsi calculés pour $N = 100$, $N = 200$ et $N = 400$ ont été présentés sous formes de tables (Tables 1, 2 et 3).

On discute ce que représente du point de vue statistique le fait de tester la signification de la différence entre deux Index Morphologiques au moyen d'une table de contingence à double entrée et d'un test de chicarré.

En se basant sur les résultats de l'examen de 66 frottis, on a trouvé que la méthode du frottis direct, largement utilisée pour l'Index Bactériologique (I.B.) peut aussi être employée pour l'examen de l'Index Morphologique.

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