3. 検査値比較 変化量比較 (52W-開始時) 完全型

		遅延型	即効型
52W-開始時 握力 左	MAX	27.00	9.50
	NMISS	2	2
	P-VALUE STUDENT T-TEST	.	0.1392
	P-VALUE Wilcoxon	.	0.0064
52W-開始時 HbA1c	N	32.00	33.00
	Mean	-0.053	-0.121
	SD	0.559	0.524
	MEDIAN	0.000	0.000
	MIN	-1.60	-2.10
	MAX	1.00	0.80
	NMISS	11	10
	P-VALUE STUDENT T-TEST	.	0.6141
	P-VALUE Wilcoxon	.	0.4685
52W-開始時 PSA	N	37.00	37.00
	Mean	0.132	0.298
	SD	0.306	0.377
	MEDIAN	0.076	0.210
	MIN	-0.36	-0.11
	MAX	1.33	1.32
	NMISS	6	6
	P-VALUE STUDENT T-TEST	.	0.0411
	P-VALUE Wilcoxon	.	0.0090

(Continued)

3. 検査値比較 変化量比較 (52W-開始時) 完全型

		遅延型	即効型
52W-開始時 膵酵素量	N	34.00	34.00
	Mean	5.445	3.200
	SD	9.207	4.304
	MEDIAN	2.300	3.000
	MIN	-4.00	-8.00
	MAX	45.94	12.00
	NMISS	9	9
	P-VALUE STUDENT T-TEST	.	0.2022
	P-VALUE Wilcoxon	.	0.8441

3. 検査値比較 変化量比較 52W-開始時 境界型

		遅延型	即効型
52W-開始時 BMI	N	17.00	23.00
	Mean	0.112	-0.065
	SD	0.892	0.771
	MEDIAN	0.100	-0.300
	MIN	-1.40	-1.20
	MAX	1.60	2.20
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.5059
	P-VALUE Wilcoxon	.	0.4031
52W-開始時 筋力（全身）	N	17.00	23.00
	Mean	0.176	0.043
	SD	1.811	1.261
	MEDIAN	0.000	0.000
	MIN	-3.00	-4.00
	MAX	5.00	2.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.7855
	P-VALUE Wilcoxon	.	0.5033
52W-開始時 筋力（腕）	N	17.00	23.00
	Mean	0.000	-0.565
	SD	1.414	1.701
	MEDIAN	0.000	0.000
	MIN	-3.00	-5.00
	MAX	3.00	2.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.2723
	P-VALUE Wilcoxon	.	0.3459
52W-開始時 筋力（脚）	N	17.00	23.00
	Mean	0.018	0.000
	SD	1.460	0.953
	MEDIAN	0.000	0.000
	MIN	-3.00	-3.00
	MAX	4.00	1.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.9634
	P-VALUE Wilcoxon	.	0.5080

(Continued)

3. 検査値比較 変化量比較 52W-開始時 境界型

		遅延型	即効型
52W-開始時 握力 右	N	17.00	23.00
	Mean	1.276	2.157
	SD	2.971	4.748
	MEDIAN	1.000	1.000
	MIN	-3.50	-6.00
	MAX	8.00	16.50
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.5057
	P-VALUE Wilcoxon	.	0.6117
52W-開始時 握力 左	N	17.00	23.00
	Mean	1.147	-0.326
	SD	2.822	6.886
	MEDIAN	1.500	2.000
	MIN	-5.50	-30.00
	MAX	6.00	3.50
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.4118
	P-VALUE Wilcoxon	.	0.9343
52W-開始時 HbA1c	N	12.00	19.00
	Mean	0.217	-0.205
	SD	0.406	0.635
	MEDIAN	0.200	-0.200
	MIN	-0.40	-1.50
	MAX	1.00	0.90
	NMISS	5	4
	P-VALUE STUDENT T-TEST	.	0.0499
	P-VALUE Wilcoxon	.	0.0533
52W-開始時 PSA	N	14.00	22.00
	Mean	0.233	0.143
	SD	0.569	0.419
	MEDIAN	0.076	0.066
	MIN	-0.77	-0.96
	MAX	1.80	1.33
	NMISS	3	1
	P-VALUE STUDENT T-TEST	.	0.5876
	P-VALUE Wilcoxon	.	0.8839

(Continued)

3. 検査値比較 変化量比較 52W-開始時 境界型

		遅延型	即効型
52W-開始時 骨塩定量	N	16.00	22.00
	Mean	2.556	3.773
	SD	6.249	5.255
	MEDIAN	2.000	2.000
	MIN	-9.00	-3.00
	MAX	15.00	18.00
	NMISS	1	1
	P-VALUE STUDENT T-TEST	.	0.5194
	P-VALUE Wilcoxon	.	0.7101

4.検査値追加項目について経時推移

全体

		分類 2			
		即時型		遅延型	
		標準誤差	平均	標準誤差	平均
Hb	開始時	0.171	14.111	0.197	13.806
	16週目	0.219	14.756	0.229	13.876
	28週目	0.213	14.854	0.207	13.997
	52週目	2.639	17.576	2.611	16.235
血糖	開始時	5.612	140.492	4.185	124.677
	16週目	5.535	137.938	5.900	128.984
	28週目	6.392	144.682	6.857	134.984
	52週目	5.956	141.661	7.642	140.947
T-Cho	開始時	3.198	182.076	3.715	187.677
	16週目	3.203	177.478	4.027	188.661
	28週目	3.892	180.545	3.826	186.100
	52週目	3.839	180.145	3.845	182.351

完全型/境界型別

			分類 2			
			即時型		遅延型	
			標準誤差	平均	標準誤差	平均
完全型	Hb	開始時	0.217	14.162	0.218	13.695
		16週目	0.286	14.886	0.264	13.723
		28週目	0.279	14.927	0.239	13.815
		52週目	4.189	19.172	3.720	17.178
	血糖	開始時	7.332	140.878	4.694	121.637
		16週目	7.574	139.341	7.385	127.714
		28週目	7.799	143.262	8.266	131.333
		52週目	8.549	143.872	9.474	137.500
	T-Cho	開始時	4.108	182.690	4.519	186.326
		16週目	4.134	175.791	4.538	187.049
		28週目	4.980	178.000	4.457	184.786
		52週目	5.217	182.795	4.423	182.075
境界型	Hb	開始時	0.295	13.991	0.451	14.206
		16週目	0.351	14.517	0.469	14.424
		28週目	0.341	14.683	0.375	14.694
		52週目	0.362	14.832	0.457	14.320
	血糖	開始時	8.833	142.304	9.320	133.471
		16週目	7.884	137.304	10.507	132.647
		28週目	11.489	149.696	12.914	141.647
		52週目	7.027	140.136	13.234	147.467
	T-Cho	開始時	5.321	180.087	7.436	190.882
		16週目	5.290	180.609	8.733	188.875
		28週目	6.464	184.174	7.951	188.412
		52週目	5.186	173.545	8.876	182.333

5. 検査値比較 追加項目 完全型

		遅延型	即効型
Hb 開始時	N	43.00	42.00
	Mean	13.695	14.162
	SD	1.432	1.407
	MEDIAN	13.700	14.100
	MIN	9.40	10.40
	MAX	16.50	16.90
	NMISS	0	1
	P-VALUE STUDENT T-TEST	.	0.1335
	P-VALUE Wilcoxon	.	0.1714
血糖 開始時	N	43.00	41.00
	Mean	121.84	140.88
	SD	30.779	56.948
	MEDIAN	111.00	126.00
	MIN	85.00	86.00
	MAX	231.00	291.00
	NMISS	0	2
	P-VALUE STUDENT T-TEST	.	0.0300
	P-VALUE Wilcoxon	.	0.0469
T-CHO 開始時	N	43.00	42.00
	Mean	186.33	182.69
	SD	29.634	28.620
	MEDIAN	186.00	183.50
	MIN	126.00	114.00
	MAX	266.00	243.00
	NMISS	0	1

(Continued)

5. 検査値比較 追加項目 完全型

		遅延型	即効型
T-CHO 開始時	P-VALUE STUDENT T-TEST	.	0.5538
	P-VALUE Wilcoxon	.	0.5917
Hb 16週目	N	40.00	42.00
	Mean	13.723	14.686
	SD	1.671	1.854
	MEDIAN	13.500	14.700
	MIN	9.80	9.40
	MAX	16.90	18.50
	NMISS	3	1
	P-VALUE STUDENT T-TEST	.	0.0038
	P-VALUE Wilcoxon	.	0.0023
血糖 16週目	N	42.00	42.00
	Mean	131.33	143.26
	SD	53.570	50.541
	MEDIAN	111.50	127.50
	MIN	67.00	93.00
	MAX	908.00	297.00
	NMISS	1	1
	P-VALUE STUDENT T-TEST	.	0.2970
	P-VALUE Wilcoxon	.	0.0764
T-CHO 16週目	N	41.00	43.00
	Mean	187.05	175.79
	SD	29.059	27.108
	MEDIAN	183.00	178.00
	MIN	131.00	118.00

(Continued)

5. 検査値比較 追加項目 完全型

		遅延型	即効型
T-CHO 16週目	MAX	242.00	230.00
	NMISS	2	0
	P-VALUE STUDENT T-TEST	.	0.0698
	P-VALUE Wilcoxon	.	0.0607
Hb 16週目-開始時の差	N	43.00	41.00
	Mean	0.090	0.746
	SD	0.804	0.953
	MEDIAN	0.200	0.700
	MIN	-1.80	-1.09
	MAX	1.90	3.70
	NMISS	3	2
	P-VALUE STUDENT T-TEST	.	0.0013
	P-VALUE Wilcoxon	.	0.0017
血糖 16週目-開始時の差	N	42.00	41.00
	Mean	9.619	2.024
	SD	45.560	41.120
	MEDIAN	3.500	3.000
	MIN	-87.00	-81.00
	MAX	197.00	172.00
	NMISS	1	2
	P-VALUE STUDENT T-TEST	.	0.4289
	P-VALUE Wilcoxon	.	0.5236

(Continued)

5. 検査値比較 追加項目 完全型

		遅延型	即効型
T-CHO 16週目-開始時の差	N	41.00	42.00
	Mean	0.220	-7.690
	SD	18.518	15.493
	MEDIAN	2.000	-7.000
	MIN	-33.00	-47.00
	MAX	47.00	20.00
	NMISS	2	1
	P-VALUE STUDENT T-TEST	.	0.0377
	P-VALUE Wilcoxon	.	0.0842
Hb 28週目	N	41.00	41.00
	Mean	13.815	14.927
	SD	1.528	1.726
	MEDIAN	13.700	15.300
	MIN	9.60	9.70
	MAX	17.00	18.40
	NMISS	2	2
	P-VALUE STUDENT T-TEST	.	0.0033
	P-VALUE Wilcoxon	.	0.0015
血糖 28週目	N	42.00	41.00
	Mean	127.71	139.34
	SD	47.860	48.495
	MEDIAN	111.50	130.00
	MIN	63.00	81.00
	MAX	259.00	319.00
	NMISS	1	2

(Continued)

5. 検査値比較 追加項目 完全型

		遅延型	即効型
血糖 28週目	P-VALUE STUDENT T-TEST	.	0.2749
	P-VALUE Wilcoxon	.	0.1942
T-CHO 28週目	N	42.00	42.00
	Mean	184.79	178.00
	SD	28.883	32.275
	MEDIAN	182.50	178.50
	MIN	122.00	108.00
	MAX	295.00	249.00
	NMISS	1	1
	P-VALUE STUDENT T-TEST	.	0.3129
	P-VALUE Wilcoxon	.	0.3209
Hb 28週目-開始時の差	N	41.00	40.00
	Mean	0.107	0.717
	SD	0.694	0.988
	MEDIAN	0.100	0.650
	MIN	-1.60	-1.10
	MAX	1.50	3.30
	NMISS	2	3
	P-VALUE STUDENT T-TEST	.	0.0018
	P-VALUE Wilcoxon	.	0.0045
血糖 28週目-開始時の差	N	42.00	40.00
	Mean	5.857	-3.800
	SD	43.714	43.051
	MEDIAN	2.000	-2.500
	MIN	-106.00	-100.00

(Continued)

5. 検査値比較 追加項目 完全型

		遅延型	即効型
血糖 28週目-開始時の差	MAX	112.00	117.00
	NMISS	1	3
	P-VALUE STUDENT T-TEST	.	0.3168
	P-VALUE Wilcoxon	.	0.2944
T-CHO 28週目-開始時の差	N	42.00	41.00
	Mean	-0.405	-5.293
	SD	22.709	22.169
	MEDIAN	2.500	-3.000
	MIN	-98.00	-54.00
	MAX	45.00	44.00
	NMISS	1	2
	P-VALUE STUDENT T-TEST	.	0.3265
	P-VALUE Wilcoxon	.	0.1564
Hb 52週目	N	40.00	38.00
	Mean	17.178	19.172
	SD	23.530	26.159
	MEDIAN	13.450	14.900
	MIN	9.90	10.90
	MAX	162.00	178.00
	NMISS	3	4
	P-VALUE STUDENT T-TEST	.	0.7225
	P-VALUE Wilcoxon	.	0.0002

(Continued)

5. 検査値比較 追加項目 完全型

		遅延型	即時型
血糖 52週目	N	40.00	39.00
	Mean	137.50	143.87
	SD	59.920	53.391
	MEDIAN	116.00	133.00
	MIN	54.00	87.00
	MAX	384.00	266.00
	NMISS	3	4
	P-VALUE STUDENT T-TEST	.	0.6195
	P-VALUE Wilcoxon	.	0.3243
T-CHO 52週目	N	40.00	39.00
	Mean	182.08	182.79
	SD	27.972	32.579
	MEDIAN	182.50	181.00
	MIN	129.00	115.00
	MAX	287.00	245.00
	NMISS	3	4
	P-VALUE STUDENT T-TEST	.	0.9163
	P-VALUE Wilcoxon	.	0.7351
Hb 52週目-開始時の差	N	40.00	38.00
	Mean	3.483	5.203
	SD	23.236	25.997
	MEDIAN	0.000	0.750
	MIN	-1.80	-1.40
	MAX	146.70	161.10
	NMISS	3	5

(Continued)

5. 検査値比較 追加項目 完全型

		遅延型	即時型
Hb 52週目-開始時の差	P-VALUE STUDENT T-TEST	.	0.7586
	P-VALUE Wilcoxon	.	<.0001
血糖52週目-開始時の差	N	40.00	37.00
	Mean	15.450	-3.081
	SD	49.844	58.325
	MEDIAN	3.500	-2.000
	MIN	-95.00	-161.00
	MAX	214.00	158.00
	NMISS	3	6
	P-VALUE STUDENT T-TEST	.	0.1372
	P-VALUE Wilcoxon	.	0.1843
T-CHO52週目-開始時の差	N	40.00	38.00
	Mean	-5.725	-0.184
	SD	21.995	24.540
	MEDIAN	-8.500	-2.500
	MIN	-75.00	-91.00
	MAX	48.00	64.00
	NMISS	3	5
	P-VALUE STUDENT T-TEST	.	0.2965
	P-VALUE Wilcoxon	.	0.1646

5. 検査値 追加項目 背景因子の比較

		分類	
		即時型	遅延型
Hb	N	66	62
	Mean	14.11	13.81
	SD	1.39	1.55
	Min	10.40	9.40
	Max	16.90	17.20
	4分位範囲	1.90	2.10
	n of missing	1	0
血糖	N	65	62
	Mean	140.49	124.68
	SD	45.25	32.96
	Min	83.00	85.00
	Max	291.00	231.00
	4分位範囲	57.00	29.00
	n of missing	2	0
T-Cho	N	66	62
	Mean	182.08	187.68
	SD	25.98	29.25
	Min	114.00	126.00
	Max	243.00	266.00
	4分位範囲	40.00	38.00
	n of missing	1	0

5. 検査値 追加項目 背景因子の比較

d7=

		分類	
		即時型	遅延型
Hb	N	1	2
	Mean	14.70	12.80
	SD	0	0.85
	Min	14.70	12.20
	Max	14.70	13.40
	4分位範囲	0.00	1.20
	n of missing	0	0
血糖	N	1	2
	Mean	83.00	111.00
	SD	0	28.28
	Min	83.00	91.00
	Max	83.00	131.00
	4分位範囲	0.00	40.00
	n of missing	0	0
T-Cho	N	1	2
	Mean	202.00	189.50
	SD	0	0.71
	Min	202.00	189.00
	Max	202.00	190.00
	4分位範囲	0.00	1.00
	n of missing	0	0

5. 検査値 追加項目 背景因子の比較

d7=完全型

		分類	
		即時型	遅延型
Hb	N	42	43
	Mean	14.16	13.70
	SD	1.41	1.45
	Min	10.40	9.40
	Max	16.90	16.50
	4分位範囲	2.20	2.10
	n of missing	1	0
血糖	N	41	43
	Mean	140.98	121.84
	SD	46.55	30.78
	Min	86.00	85.00
	Max	291.00	231.00
	4分位範囲	52.00	31.00
	n of missing	2	0
T-Cho	N	42	43
	Mean	182.69	186.33
	SD	26.62	29.63
	Min	114.00	126.00
	Max	243.00	266.00
	4分位範囲	36.00	38.00
	n of missing	1	0

5. 検査値 追加項目 背景因子の比較

d7=境界型

		分類	
		即時型	遅延型
Hb	N	23	17
	Mean	13.99	14.21
	SD	1.41	1.66
	Min	11.40	9.90
	Max	16.30	17.20
	4分位範囲	2.10	2.10
	n of missing	0	0
血糖	N	23	17
	Mean	142.30	133.47
	SD	42.36	38.49
	Min	84.00	85.00
	Max	236.00	212.00
	4分位範囲	62.00	28.00
	n of missing	0	0
T-Cho	N	23	17
	Mean	180.09	190.88
	SD	25.52	30.66
	Min	146.00	142.00
	Max	235.00	253.00
	4分位範囲	46.00	53.00
	n of missing	0	0

5. 検査値比較 追加項目

		遅延型	即効型
Hb 開始時	N	62.00	66.00
	Mean	13.809	14.111
	SD	1.555	1.381
	MEDIAN	13.750	14.250
	MIN	9.40	10.40
	MAX	17.20	16.90
	NMISS	0	1
	P-VALUE STUDENT T-TEST		0.2451
	P-VALUE Wilcoxon		0.2842
血糖 開始時	N	62.00	65.00
	Mean	124.68	140.49
	SD	92.958	45.247
	MEDIAN	115.00	128.00
	MIN	65.00	83.00
	MAX	231.00	291.00
	NMISS	0	2
	P-VALUE STUDENT T-TEST		0.0267
	P-VALUE Wilcoxon		0.0439
T-CHO 開始時	N	62.00	66.00
	Mean	187.68	182.08
	SD	28.248	25.954
	MEDIAN	187.50	183.00
	MIN	126.00	114.00
	MAX	265.00	243.00
	NMISS	0	1

(Continued)

5. 検査値比較 追加項目

		遅延型	即効型
T-CHO 開始時	P-VALUE STUDENT T-TEST		0.2535
	P-VALUE Wilcoxon		0.3098
Hb 16週目	N	59.00	66.00
	Mean	13.878	14.758
	SD	1.761	1.777
	MEDIAN	13.600	14.700
	MIN	9.80	9.40
	MAX	17.90	18.50
	NMISS	3	1
	P-VALUE STUDENT T-TEST		0.0054
	P-VALUE Wilcoxon		0.0035
血糖 16週目	N	61.00	66.00
	Mean	134.98	144.68
	SD	59.557	51.929
	MEDIAN	114.00	130.00
	MIN	67.00	57.00
	MAX	306.00	300.00
	NMISS	1	1
	P-VALUE STUDENT T-TEST		0.3023
	P-VALUE Wilcoxon		0.0761
T-CHO 16週目	N	59.00	67.00
	Mean	188.66	177.48
	SD	30.935	26.219
	MEDIAN	187.00	178.00
	MIN	131.00	118.00

(Continued)

5. 検査値比較 追加項目

		遅延型	即効型
T-CHO 16週目	MAX	268.00	230.00
	NMISS	3	0
	P-VALUE STUDENT T-TEST		0.0299
	P-VALUE Wilcoxon		0.0568
Hb 16週目-開始時の差	N	59.00	65.00
	Mean	0.107	0.658
	SD	0.803	0.699
	MEDIAN	0.200	0.700
	MIN	-1.80	-1.00
	MAX	1.90	3.70
	NMISS	3	2
	P-VALUE STUDENT T-TEST		0.0005
	P-VALUE Wilcoxon		0.0007
血糖 16週目-開始時の差	N	61.00	65.00
	Mean	10.344	3.955
	SD	47.054	43.330
	MEDIAN	4.000	5.000
	MIN	-133.00	-125.00
	MAX	197.00	172.00
	NMISS	1	2
	P-VALUE STUDENT T-TEST		0.4313
	P-VALUE Wilcoxon		0.7929

(Continued)

5. 検査値比較 追加項目

		遅延型	即効型
T-CHO 16週目-開始時の差	N	59.00	65.00
	Mean	0.458	-5.079
	SD	18.861	16.748
	MEDIAN	2.000	-5.500
	MIN	-33.00	-47.00
	MAX	56.00	43.00
	NMISS	3	1
	P-VALUE STUDENT T-TEST		0.0648
	P-VALUE Wilcoxon		0.1288
Hb 28週目	N	60.00	65.00
	Mean	13.997	14.854
	SD	1.604	1.715
	MEDIAN	14.050	15.000
	MIN	9.60	9.70
	MAX	18.30	18.40
	NMISS	2	2
	P-VALUE STUDENT T-TEST		0.0047
	P-VALUE Wilcoxon		0.0019
血糖 28週目	N	61.00	65.00
	Mean	128.98	137.94
	SD	48.079	44.626
	MEDIAN	113.00	130.00
	MIN	63.00	81.00
	MAX	259.00	319.00
	NMISS	1	2

(Continued)

5. 検査値比較 追加項目

		遅延型	即効型
血糖 28週目	P-VALUE STUDENT T-TEST		0.2700
	P-VALUE Wilcoxon		0.1708
T-CHO 28週目	N	60.00	66.00
	Mean	186.10	180.55
	SD	29.696	31.618
	MEDIAN	184.50	179.50
	MIN	122.00	108.00
	MAX	265.00	249.00
	NMISS	2	1
	P-VALUE STUDENT T-TEST		0.3123
	P-VALUE Wilcoxon		0.3225
Hb 28週目-開始時の差	N	60.00	64.00
	Mean	0.178	0.714
	SD	0.695	0.914
	MEDIAN	0.200	0.600
	MIN	-2.90	-1.10
	MAX	4.20	3.30
	NMISS	2	3
	P-VALUE STUDENT T-TEST		0.0012
	P-VALUE Wilcoxon		0.0009
血糖 28週目-開始時の差	N	61.00	64.00
	Mean	4.246	-3.984
	SD	39.789	43.335
	MEDIAN	2.000	1.000
	MIN	-106.00	-108.00

(Continued)

5. 検査値比較 追加項目

		遅延型	即効型
血糖 28週目-開始時の差	MAX	112.00	117.00
	NMISS	1	3
	P-VALUE STUDENT T-TEST		0.2715
	P-VALUE Wilcoxon		0.3266
T-CHO 28週目-開始時の差	N	60.00	65.00
	Mean	-0.783	-1.862
	SD	20.635	23.009
	MEDIAN	1.000	0.000
	MIN	-98.00	-54.00
	MAX	45.00	65.00
	NMISS	2	2
	P-VALUE STUDENT T-TEST		0.7838
	P-VALUE Wilcoxon		0.3775
Hb 52週目	N	57.00	62.00
	Mean	16.235	17.576
	SD	19.715	23.777
	MEDIAN	13.500	14.950
	MIN	9.90	10.60
	MAX	162.00	178.00
	NMISS	5	5
	P-VALUE STUDENT T-TEST		0.7192
	P-VALUE Wilcoxon		<.0001

(Continued)

5. 検査値比較 追加項目

		遅延型	即効型
血糖 52週目	N	57.00	62.00
	Mean	140.95	141.66
	SD	57.695	46.896
	MEDIAN	119.00	135.00
	MIN	54.00	87.00
	MAX	384.00	286.00
	NMISS	5	5
	P-VALUE STUDENT T-TEST		0.9409
	P-VALUE Wilcoxon		0.4420
T-CHO 52週目	N	57.00	62.00
	Mean	182.35	180.15
	SD	28.031	30.229
	MEDIAN	185.00	180.50
	MIN	116.00	115.00
	MAX	267.00	245.00
	NMISS	5	5
	P-VALUE STUDENT T-TEST		0.6960
	P-VALUE Wilcoxon		0.6997
Hb 52週目-開始時の差	N	57.00	61.00
	Mean	2.440	3.523
	SD	19.471	20.539
	MEDIAN	0.000	0.800
	MIN	-2.10	-1.40
	MAX	148.70	161.10
	NMISS	5	6

(Continued)

5. 検査値比較 追加項目

		遅延型	即効型
Hb 52週目-開始時の差	P-VALUE STUDENT T-TEST		0.7698
	P-VALUE Wilcoxon		<.0001
血糖52週目-開始時の差	N	57.00	60.00
	Mean	18.211	-3.150
	SD	44.725	49.945
	MEDIAN	5.000	0.500
	MIN	-95.00	-161.00
	MAX	214.00	138.00
	NMISS	5	7
	P-VALUE STUDENT T-TEST		0.0295
	P-VALUE Wilcoxon		0.0858
T-CHO52週目-開始時の差	N	57.00	61.00
	Mean	-6.058	-1.721
	SD	21.455	21.253
	MEDIAN	-7.000	-5.000
	MIN	-75.00	-91.00
	MAX	48.00	64.00
	NMISS	5	6
	P-VALUE STUDENT T-TEST		0.2692
	P-VALUE Wilcoxon		0.2765

5. 検査値比較 追加項目 境界型

		遅延型	即効型
Hb 開始時	N	17.00	23.00
	Mean	14.206	13.991
	SD	1.850	1.413
	MEDIAN	14.500	14.500
	MIN	9.90	11.40
	MAX	17.20	16.30
	NMISS	0	0
	P-VALUE STUDENT T-TEST		0.6804
	P-VALUE Wilcoxon		0.5469
血糖 開始時	N	17.00	23.00
	Mean	133.47	142.30
	SD	38.429	42.358
	MEDIAN	124.00	130.00
	MIN	85.00	84.00
	MAX	212.00	236.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST		0.5020
	P-VALUE Wilcoxon		0.5563
T-CHO 開始時	N	17.00	23.00
	Mean	190.88	180.09
	SD	30.659	25.520
	MEDIAN	195.00	173.00
	MIN	142.00	146.00
	MAX	253.00	235.00
	NMISS	0	0

(Continued)

5. 検査値比較 追加項目 境界型

		遅延型	即効型
T-CHO 開始時	P-VALUE STUDENT T-TEST		0.2322
	P-VALUE Wilcoxon		0.2502
Hb 16週目	N	17.00	23.00
	Mean	14.424	14.517
	SD	1.934	1.682
	MEDIAN	14.100	14.700
	MIN	11.40	11.40
	MAX	17.90	18.20
	NMISS	0	0
	P-VALUE STUDENT T-TEST		0.8708
	P-VALUE Wilcoxon		0.8054
血糖 16週目	N	17.00	23.00
	Mean	141.65	149.70
	SD	53.245	55.099
	MEDIAN	127.00	137.00
	MIN	71.00	57.00
	MAX	276.00	300.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST		0.6459
	P-VALUE Wilcoxon		0.4939
T-CHO 16週目	N	16.00	23.00
	Mean	166.88	180.61
	SD	34.930	25.370
	MEDIAN	189.50	170.00
	MIN	137.00	143.00

(Continued)

5. 検査値比較 追加項目 境界型

		遅延型	即効型
T-CHO 16週目	MAX	268.00	225.00
	NMISS	1	0
	P-VALUE STUDENT T-TEST		0.3969
	P-VALUE Wilcoxon		0.5776
Hb 16週目-開始時の差	N	17.00	23.00
	Mean	0.218	0.526
	SD	0.787	0.806
	MEDIAN	0.100	0.500
	MIN	-1.09	-0.99
	MAX	1.80	1.90
	NMISS	0	0
	P-VALUE STUDENT T-TEST		0.2344
	P-VALUE Wilcoxon		0.2028
血糖 16週目-開始時の差	N	17.00	23.00
	Mean	8.176	7.391
	SD	51.538	48.664
	MEDIAN	6.000	13.000
	MIN	-133.00	-125.00
	MAX	94.00	92.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST		0.9510
	P-VALUE Wilcoxon		0.6615

(Continued)

5. 検査値比較 追加項目 境界型

		遅延型	即効型
T-CHO 16週目-開始時の差	N	16.00	23.00
	Mean	-2.688	0.522
	SD	15.598	17.870
	MEDIAN	-0.900	3.000
	MIN	-33.00	-31.00
	MAX	22.00	43.00
	NMISS	1	0
	P-VALUE STUDENT T-TEST		0.5652
	P-VALUE Wilcoxon		0.6682
Hb 28週目	N	17.00	23.00
	Mean	14.694	14.683
	SD	1.545	1.636
	MEDIAN	14.500	14.900
	MIN	11.30	11.20
	MAX	18.30	18.40
	NMISS	0	0
	P-VALUE STUDENT T-TEST		0.9822
	P-VALUE Wilcoxon		0.8480
血糖 28週目	N	17.00	23.00
	Mean	132.65	137.30
	SD	43.309	37.809
	MEDIAN	122.00	135.00
	MIN	83.00	85.00
	MAX	244.00	218.00
	NMISS	0	0

(Continued)

5. 検査値比較 追加項目 境界型

		遅延型	即効型
血糖 28週目	P-VALUE STUDENT T-TEST	.	0.7193
	P-VALUE Wilcoxon	.	0.5841
T-CHO 28週目	N	17.00	23.00
	Mean	188.41	184.17
	SD	32.752	31.001
	MEDIAN	190.00	182.00
	MIN	126.00	129.00
	MAX	245.00	230.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.6799
	P-VALUE Wilcoxon	.	0.6615
Hb 28週目-開始時の差	N	17.00	23.00
	Mean	0.488	0.691
	SD	1.068	0.809
	MEDIAN	0.300	0.600
	MIN	-0.60	-0.80
	MAX	4.20	2.40
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.5029
	P-VALUE Wilcoxon	.	0.2074
血糖 28週目-開始時の差	N	17.00	23.00
	Mean	-0.824	-5.000
	SD	30.796	45.601
	MEDIAN	-2.000	4.000
	MIN	-52.00	-108.00

(Continued)

5. 検査値比較 追加項目 境界型

		遅延型	即効型
血糖 28週目-開始時の差	MAX	44.00	109.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.7461
	P-VALUE Wilcoxon	.	0.9455
T-CHO 28週目-開始時の差	N	17.00	23.00
	Mean	-2.471	4.087
	SD	15.330	23.855
	MEDIAN	-5.000	3.000
	MIN	-25.00	-37.00
	MAX	28.00	65.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.3282
	P-VALUE Wilcoxon	.	0.5113
Hb 52週目	N	15.00	22.00
	Mean	14.320	14.832
	SD	1.768	1.700
	MEDIAN	14.600	14.950
	MIN	11.00	10.60
	MAX	17.30	17.40
	NMISS	2	1
	P-VALUE STUDENT T-TEST	.	0.3823
	P-VALUE Wilcoxon	.	0.3069

(Continued)

5. 検査値比較 追加項目 境界型

		遅延型	即効型
血糖 52週目	N	15.00	22.00
	Mean	147.47	140.14
	SD	51.257	32.961
	MEDIAN	130.00	137.00
	MIN	94.00	93.00
	MAX	263.00	205.00
	NMISS	2	1
	P-VALUE STUDENT T-TEST	.	0.5981
	P-VALUE Wilcoxon	.	0.9753
T-CHO 52週目	N	15.00	22.00
	Mean	182.33	173.55
	SD	34.375	24.323
	MEDIAN	187.00	176.50
	MIN	118.00	132.00
	MAX	228.00	218.00
	NMISS	2	1
	P-VALUE STUDENT T-TEST	.	0.3679
	P-VALUE Wilcoxon	.	0.2099
Hb 52週目-開始時の差	N	15.00	22.00
	Mean	0.127	0.736
	SD	1.323	0.939
	MEDIAN	-0.200	0.600
	MIN	-0.90	-1.20
	MAX	4.70	2.30
	NMISS	2	1

(Continued)

5. 検査値比較 追加項目 境界型

		遅延型	即効型
Hb 52週目-開始時の差	P-VALUE STUDENT T-TEST	.	0.1095
	P-VALUE Wilcoxon	.	0.0053
血糖52週目-開始時の差	N	15.00	22.00
	Mean	13.733	-3.682
	SD	25.631	34.238
	MEDIAN	5.000	2.000
	MIN	-19.00	-100.00
	MAX	56.00	58.00
	NMISS	2	1
	P-VALUE STUDENT T-TEST	.	0.1032
	P-VALUE Wilcoxon	.	0.2520
T-CHO52週目-開始時の差	N	15.00	22.00
	Mean	-7.667	-5.364
	SD	21.983	13.741
	MEDIAN	-1.000	-7.000
	MIN	-60.00	-32.00
	MAX	23.00	23.00
	NMISS	2	1
	P-VALUE STUDENT T-TEST	.	0.6958
	P-VALUE Wilcoxon	.	0.9629

5. 検査値比較 追加項目 境界型

		遅延型	即効型
Hb 開始時	N	17.00	23.00
	Mean	14.206	13.991
	SD	1.680	1.413
	MEDIAN	14.500	14.500
	MIN	9.90	11.40
	MAX	17.20	16.90
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.6804
	P-VALUE Wilcoxon	.	0.5488
血糖 開始時	N	17.00	23.00
	Mean	133.47	142.30
	SD	38.429	42.359
	MEDIAN	124.00	130.00
	MIN	85.00	84.00
	MAX	212.00	238.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.5020
	P-VALUE Wilcoxon	.	0.5563
T-CHO 開始時	N	17.00	23.00
	Mean	190.88	180.09
	SD	30.859	25.520
	MEDIAN	195.00	173.00
	MIN	142.00	146.00
	MAX	253.00	235.00
	NMISS	0	0

(Continued)

5. 検査値比較 追加項目 境界型

		遅延型	即効型
T-CHO 開始時	P-VALUE STUDENT T-TEST	.	0.2322
	P-VALUE Wilcoxon	.	0.2502
Hb 16週目	N	17.00	23.00
	Mean	14.424	14.517
	SD	1.934	1.682
	MEDIAN	14.100	14.700
	MIN	11.40	11.40
	MAX	17.90	18.20
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.8708
	P-VALUE Wilcoxon	.	0.8054
血糖 16週目	N	17.00	23.00
	Mean	141.65	149.70
	SD	53.245	55.099
	MEDIAN	127.00	137.00
	MIN	71.00	57.00
	MAX	276.00	300.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.6459
	P-VALUE Wilcoxon	.	0.4939
T-CHO 16週目	N	16.00	23.00
	Mean	168.88	180.61
	SD	34.930	25.370
	MEDIAN	168.50	170.00
	MIN	137.00	143.00

(Continued)

5. 検査値比較 追加項目 境界型

		遅延型	即効型
T-CHO 16週目	MAX	268.00	225.00
	NMISS	1	0
	P-VALUE STUDENT T-TEST	.	0.3968
	P-VALUE Wilcoxon	.	0.5776
Hb 16週目-開始時の差	N	17.00	23.00
	Mean	0.218	0.526
	SD	0.787	0.896
	MEDIAN	0.100	0.500
	MIN	-1.00	-0.90
	MAX	1.80	1.90
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.2344
	P-VALUE Wilcoxon	.	0.2026
血糖 16週目-開始時の差	N	17.00	23.00
	Mean	8.176	7.391
	SD	51.538	48.664
	MEDIAN	8.000	13.000
	MIN	-133.00	-125.00
	MAX	94.00	92.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.9510
	P-VALUE Wilcoxon	.	0.6615

(Continued)

5. 検査値比較 追加項目 境界型

		遅延型	即効型
T-CHO 16週目-開始時の差	N	16.00	23.00
	Mean	-2.668	0.522
	SD	15.598	17.870
	MEDIAN	-0.500	3.000
	MIN	-33.00	-31.00
	MAX	22.00	43.00
	NMISS	1	0
	P-VALUE STUDENT T-TEST	.	0.5652
	P-VALUE Wilcoxon	.	0.6682
Hb 28週目	N	17.00	23.00
	Mean	14.694	14.683
	SD	1.545	1.636
	MEDIAN	14.500	14.900
	MIN	11.30	11.20
	MAX	18.30	18.40
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.9822
	P-VALUE Wilcoxon	.	0.6480
血糖 28週目	N	17.00	23.00
	Mean	132.65	137.30
	SD	43.320	37.809
	MEDIAN	122.00	136.00
	MIN	83.00	85.00
	MAX	244.00	218.00
	NMISS	0	0

(Continued)

5. 検査値比較 追加項目 境界型

		遅延型	即効型
血糖 28週目	P-VALUE STUDENT T-TEST	.	0.7193
	P-VALUE Wilcoxon	.	0.5841
T-CHO 28週目	N	17.00	23.00
	Mean	188.41	184.17
	SD	32.782	31.001
	MEDIAN	190.00	182.00
	MIN	126.00	120.00
	MAX	245.00	230.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.6789
	P-VALUE Wilcoxon	.	0.6615
Hb 28週目-開始時の差	N	17.00	23.00
	Mean	0.488	0.691
	SD	1.058	0.809
	MEDIAN	0.300	0.600
	MIN	-0.60	-0.60
	MAX	4.20	2.40
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.5020
	P-VALUE Wilcoxon	.	0.2074
血糖 28週目-開始時の差	N	17.00	23.00
	Mean	-0.824	-5.000
	SD	30.736	45.601
	MEDIAN	-2.000	4.000
	MIN	-52.00	-108.00

(Continued)

5. 検査値比較 追加項目 境界型

		遅延型	即効型
血糖 28週目-開始時の差	MAX	44.00	109.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.7461
	P-VALUE Wilcoxon	.	0.9455
T-CHO 28週目-開始時の差	N	17.00	23.00
	Mean	-2.471	4.087
	SD	15.330	23.855
	MEDIAN	-5.000	3.000
	MIN	-25.00	-37.00
	MAX	28.00	65.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.3282
	P-VALUE Wilcoxon	.	0.5119
Hb 52週目	N	15.00	22.00
	Mean	14.320	14.832
	SD	1.768	1.700
	MEDIAN	14.600	14.950
	MIN	11.00	10.60
	MAX	17.30	17.40
	NMISS	2	1
	P-VALUE STUDENT T-TEST	.	0.3823
	P-VALUE Wilcoxon	.	0.5069

(Continued)

5. 検査値比較 追加項目 境界型

		遅延型	即効型
血糖 52週目	N	15.00	22.00
	Mean	147.47	140.14
	SD	51.257	32.961
	MEDIAN	150.00	137.00
	MIN	94.00	93.00
	MAX	263.00	205.00
	NMISS	2	1
	P-VALUE STUDENT T-TEST	.	0.5991
	P-VALUE Wilcoxon	.	0.9753
T-CHO 52週目	N	15.00	22.00
	Mean	182.33	173.55
	SD	34.975	24.923
	MEDIAN	187.00	178.50
	MIN	116.00	132.00
	MAX	228.00	218.00
	NMISS	2	1
	P-VALUE STUDENT T-TEST	.	0.3679
	P-VALUE Wilcoxon	.	0.2099
Hb 52週目-開始時の差	N	15.00	22.00
	Mean	0.127	0.736
	SD	1.323	0.938
	MEDIAN	-0.200	0.800
	MIN	-0.90	-1.20
	MAX	4.70	2.30
	NMISS	2	1

(Continued)

5. 検査値比較 追加項目 境界型

		遅延型	即効型
Hb 52週目-開始時の差	P-VALUE STUDENT T-TEST	.	0.1095
	P-VALUE Wilcoxon	.	0.0053
血糖52週目-開始時の差	N	15.00	22.00
	Mean	13.733	-1.682
	SD	25.631	34.238
	MEDIAN	5.000	2.000
	MIN	-19.00	-100.00
	MAX	56.00	58.00
	NMISS	2	1
	P-VALUE STUDENT T-TEST	.	0.1032
	P-VALUE Wilcoxon	.	0.2520
T-CH52週目-開始時の差	N	15.00	22.00
	Mean	-7.667	-5.364
	SD	21.983	13.741
	MEDIAN	-1.000	-7.000
	MIN	-60.00	-32.00
	MAX	23.00	23.00
	NMISS	2	1
	P-VALUE STUDENT T-TEST	.	0.6958
	P-VALUE Wilcoxon	.	0.9629

6. QOL比較 52週目 完全型

		遅延型	即効型
PF	N	40.00	35.00
	Mean	83.687	90.857
	SD	17.794	10.109
	MEDIAN	90.000	95.000
	MIN	20.00	60.00
	MAX	100.00	100.00
	NMISS	3	8
	P-VALUE STUDENT T-TEST	.	0.0383
	P-VALUE Wilcoxon	.	0.0186
PR	N	40.00	35.00
	Mean	85.781	91.429
	SD	22.378	12.958
	MEDIAN	100.00	100.00
	MIN	31.25	56.25
	MAX	100.00	100.00
	NMISS	3	8
	P-VALUE STUDENT T-TEST	.	0.1936
	P-VALUE Wilcoxon	.	0.6396
BP	N	40.00	34.00
	Mean	74.025	75.853
	SD	25.996	20.207
	MEDIAN	78.000	73.000
	MIN	21.00	31.00
	MAX	100.00	100.00
	NMISS	3	9

(Continued)

6. QOL比較 52週目 完全型

		遅延型	即効型
BP	P-VALUE STUDENT T-TEST	.	0.7400
	P-VALUE Wilcoxon	.	0.8234
CH	N	38.00	35.00
	Mean	61.595	60.214
	SD	19.959	16.838
	MEDIAN	57.000	57.000
	MIN	17.00	20.00
	MAX	100.00	97.00
	NMISS	4	8
	P-VALUE STUDENT T-TEST	.	0.7499
	P-VALUE Wilcoxon	.	0.9005
VT	N	38.00	35.00
	Mean	71.688	68.929
	SD	18.423	19.382
	MEDIAN	75.000	68.750
	MIN	25.00	31.25
	MAX	100.00	100.00
	NMISS	4	8
	P-VALUE STUDENT T-TEST	.	0.5322
	P-VALUE Wilcoxon	.	0.5481
SF	N	40.00	34.00
	Mean	82.188	86.765
	SD	26.688	19.929
	MEDIAN	100.00	100.00
	MIN	12.50	37.50

(Continued)

6. QOL比較 52週目 完全型

		遅延型	即効型
SF	MAX	100.00	100.00
	NMISS	3	9
	P-VALUE STUDENT T-TEST	.	0.4130
	P-VALUE Wilcoxon	.	0.6625
RE	N	39.00	35.00
	Mean	89.316	91.150
	SD	19.398	11.775
	MEDIAN	100.00	100.00
	MIN	16.67	66.67
	MAX	100.00	100.00
	NMISS	4	8
	P-VALUE STUDENT T-TEST	.	0.6219
	P-VALUE Wilcoxon	.	0.6494
MH	N	39.00	35.00
	Mean	80.385	77.429
	SD	16.339	18.525
	MEDIAN	85.000	85.000
	MIN	40.00	35.00
	MAX	100.00	100.00
	NMISS	4	8
	P-VALUE STUDENT T-TEST	.	0.4689
	P-VALUE Wilcoxon	.	0.5671

(Continued)

6. QOL比較 52週目 完全型

		遅延型	即効型
AMS (心理的)	N	43.00	43.00
	Mean	7.070	6.395
	SD	3.801	4.101
	MEDIAN	7.000	7.000
	MIN	0.00	0.00
	MAX	19.00	15.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.4312
	P-VALUE Wilcoxon	.	0.7833
AMS (身体的)	N	43.00	43.00
	Mean	12.000	11.628
	SD	5.434	7.241
	MEDIAN	12.000	14.000
	MIN	0.00	0.00
	MAX	21.00	23.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.7882
	P-VALUE Wilcoxon	.	0.8363
AMS (性機能)	N	43.00	43.00
	Mean	12.395	10.837
	SD	5.729	6.750
	MEDIAN	13.000	13.000
	MIN	0.00	0.00
	MAX	22.00	21.00
	NMISS	0	0

(Continued)

6. QOL比較 52週目 完全型

		遅延型	即効型
AMS (性機能)	P-VALUE STUDENT T-TEST	.	0.2518
	P-VALUE Wilcoxon	.	0.4560
国際前立腺症状スコア計	N	43.00	43.00
	Mean	12.023	9.140
	SD	9.987	9.491
	MEDIAN	9.000	6.000
	MIN	0.00	0.00
	MAX	34.00	33.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.1735
	P-VALUE Wilcoxon	.	0.1242
国際勃起能スコア5	N	43.00	43.00
	Mean	5.442	8.884
	SD	5.599	7.632
	MEDIAN	4.000	8.000
	MIN	0.00	0.00
	MAX	18.00	24.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.0194
	P-VALUE Wilcoxon	.	0.0423

6. QOL比較 52週目 境界型

		遅延型	即効型
PF	N	13.00	19.00
	Mean	85.000	91.053
	SD	11.902	7.742
	MEDIAN	85.000	95.000
	MIN	60.00	70.00
	MAX	100.00	100.00
	NMISS	4	4
	P-VALUE STUDENT T-TEST	.	0.0908
	P-VALUE Wilcoxon	.	0.1326
PR	N	13.00	19.00
	Mean	82.692	92.763
	SD	37.077	13.661
	MEDIAN	100.00	100.00
	MIN	0.00	50.00
	MAX	100.00	100.00
	NMISS	4	4
	P-VALUE STUDENT T-TEST	.	0.2856
	P-VALUE Wilcoxon	.	0.9070
BP	N	13.00	19.00
	Mean	78.615	72.632
	SD	22.500	18.670
	MEDIAN	84.000	72.000
	MIN	22.00	32.00
	MAX	100.00	100.00
	NMISS	4	4

(Continued)

6. QOL比較 52週目 境界型

		遅延型	即効型
BP	P-VALUE STUDENT T-TEST	.	0.4190
	P-VALUE Wilcoxon	.	0.2116
GH	N	14.00	18.00
	Mean	59.571	59.278
	SD	17.526	13.655
	MEDIAN	54.500	57.000
	MIN	32.00	42.00
	MAX	87.50	100.00
	NMISS	3	5
	P-VALUE STUDENT T-TEST	.	0.9578
	P-VALUE Wilcoxon	.	1.0000
VT	N	14.00	18.00
	Mean	70.536	71.181
	SD	28.678	16.205
	MEDIAN	78.125	75.000
	MIN	6.25	43.75
	MAX	100.00	100.00
	NMISS	3	5
	P-VALUE STUDENT T-TEST	.	0.9331
	P-VALUE Wilcoxon	.	0.4893
SF	N	14.00	18.00
	Mean	81.250	84.868
	SD	30.912	23.041
	MEDIAN	100.00	100.00
	MIN	12.50	50.00

(Continued)

6. QOL比較 52週目 境界型

		遅延型	即効型
SF	MAX	100.00	100.00
	NMISS	3	4
	P-VALUE STUDENT T-TEST	.	0.7023
	P-VALUE Wilcoxon	.	0.7769
RE	N	12.00	18.00
	Mean	88.194	92.105
	SD	28.968	13.168
	MEDIAN	100.00	100.00
	MIN	0.00	50.00
	MAX	100.00	100.00
	NMISS	5	4
	P-VALUE STUDENT T-TEST	.	0.6112
	P-VALUE Wilcoxon	.	0.5069
MH	N	14.00	18.00
	Mean	74.286	74.722
	SD	23.440	13.466
	MEDIAN	85.000	75.000
	MIN	25.00	50.00
	MAX	95.00	90.00
	NMISS	3	5
	P-VALUE STUDENT T-TEST	.	0.9475
	P-VALUE Wilcoxon	.	0.4091

(Continued)

6. QOL比較 52週目 境界型

		遅延型	即効型
AMS (心理的)	N	17.00	23.00
	Mean	5.824	6.652
	SD	3.340	3.973
	MEDIAN	6.000	7.000
	MIN	0.00	0.00
	MAX	11.00	15.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.4903
	P-VALUE Wilcoxon	.	0.4384
AMS (身体的)	N	17.00	23.00
	Mean	11.176	12.957
	SD	6.673	7.491
	MEDIAN	12.000	14.000
	MIN	0.00	0.00
	MAX	25.00	26.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.4384
	P-VALUE Wilcoxon	.	0.2314
AMS (性機能)	N	17.00	23.00
	Mean	10.765	10.739
	SD	6.369	5.879
	MEDIAN	12.000	13.000
	MIN	0.00	0.00
	MAX	19.00	19.00
	NMISS	0	0

(Continued)

6. QOL比較 52週目 境界型

		遅延型	即効型
AMS (性機能)	P-VALUE STUDENT T-TEST	.	0.9896
	P-VALUE Wilcoxon	.	0.9233
国際前立腺症状スコア計	N	17.00	23.00
	Mean	6.235	7.522
	SD	5.828	8.011
	MEDIAN	5.000	6.000
	MIN	0.00	0.00
	MAX	19.00	30.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.5762
	P-VALUE Wilcoxon	.	0.7832
国際勃起能スコア5	N	17.00	23.00
	Mean	7.235	8.652
	SD	7.957	7.774
	MEDIAN	5.000	9.000
	MIN	0.00	0.00
	MAX	21.00	24.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.5743
	P-VALUE Wilcoxon	.	0.4534

6. QOL比較 差の変化量 (52W-開始時) 完全型

			遅延型	即効型
52W-開始時	PF	N	38.00	33.00
		Mean	-0.192	-1.785
		SD	11.652	7.821
		MEDIAN	0.000	0.000
		MIN	-40.00	-35.00
		MAX	20.00	6.11
		NMISS	4	10
		P-VALUE STUDENT T-TEST		0.5066
		P-VALUE Wilcoxon		0.1921
52W-開始時	PR	N	38.00	34.00
		Mean	-1.316	2.941
		SD	18.843	17.958
		MEDIAN	0.000	0.000
		MIN	-68.75	-43.75
		MAX	37.50	43.75
		NMISS	5	9
		P-VALUE STUDENT T-TEST		0.3313
		P-VALUE Wilcoxon		0.3134
52W-開始時	BP	N	38.00	33.00
		Mean	-2.000	1.030
		SD	23.418	22.971
		MEDIAN	0.000	0.000
		MIN	-58.00	-38.00
		MAX	48.00	69.00
		NMISS	4	10

(Continued)

6. QOL比較 差の変化量 (52W-開始時) 完全型

			遅延型	即効型
52W-開始時	BP	P-VALUE STUDENT T-TEST		0.5828
		P-VALUE Wilcoxon		0.8499
52W-開始時	GH	N	38.00	35.00
		Mean	-0.628	3.579
		SD	15.434	12.133
		MEDIAN	0.000	5.000
		MIN	-37.00	-22.00
		MAX	35.00	40.00
		NMISS	5	8
		P-VALUE STUDENT T-TEST	.	0.2747
		P-VALUE Wilcoxon	.	0.3374
52W-開始時	VT	N	38.00	35.00
		Mean	-0.932	1.964
		SD	19.457	19.280
		MEDIAN	0.000	0.000
		MIN	-50.00	-43.75
		MAX	43.75	50.00
		NMISS	5	8
		P-VALUE STUDENT T-TEST	.	0.5254
		P-VALUE Wilcoxon	.	0.6662
52W-開始時	SF	N	38.00	34.00
		Mean	-1.603	2.206
		SD	26.929	20.289
		MEDIAN	0.000	0.000
		MIN	-75.00	-37.50

(Continued)

6. QOL比較　差の変化量（52W-開始時）完全型

		遅延型	即効型
52W-開始時　SF	MAX	50.00	50.00
	NMISS	4	9
	P-VALUE STUDENT T-TEST	.	0.5023
	P-VALUE Wilcoxon	.	0.7378
52W-開始時　RE	N	38.00	34.00
	Mean	-2.193	2.451
	SD	19.978	16.223
	MEDIAN	0.000	0.000
	MIN	-58.33	-33.33
	MAX	58.33	41.67
	NMISS	5	9
	P-VALUE STUDENT T-TEST	.	0.2853
	P-VALUE Wilcoxon	.	0.2390
52W-開始時　MH	N	38.00	35.00
	Mean	3.553	2.821
	SD	16.882	17.073
	MEDIAN	0.000	0.000
	MIN	-30.00	-30.00
	MAX	50.00	60.00
	NMISS	5	8
	P-VALUE STUDENT T-TEST	.	0.8546
	P-VALUE Wilcoxon	.	0.9334

(Continued)

6. QOL比較　差の変化量（52W-開始時）完全型

		遅延型	即効型
52W-開始時　AMS(心理的)	N	43.00	43.00
	Mean	-0.953	-2.163
	SD	3.909	4.908
	MEDIAN	0.000	0.000
	MIN	-14.00	-17.00
	MAX	9.00	5.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.2098
	P-VALUE Wilcoxon	.	0.4946
52W-開始時　AMS(身体的)	N	43.00	43.00
	Mean	-1.349	-3.233
	SD	5.802	8.904
	MEDIAN	-1.000	-1.000
	MIN	-15.00	-27.00
	MAX	13.00	21.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.2484
	P-VALUE Wilcoxon	.	0.4681
52W-開始時　AMS(性機能)	N	43.00	43.00
	Mean	-1.256	-3.209
	SD	6.507	7.903
	MEDIAN	0.000	-2.000
	MIN	-18.00	-22.00
	MAX	12.00	21.00
	NMISS	0	0

(Continued)

6. QOL比較　差の変化量（52W-開始時）完全型

		遅延型	即効型
52W-開始時　AMS(性機能)	P-VALUE STUDENT T-TEST	.	0.2143
	P-VALUE Wilcoxon	.	0.1157
52W-開始時　国際前立腺症状スコア計	N	43.00	43.00
	Mean	1.209	-2.279
	SD	6.089	7.679
	MEDIAN	0.000	-1.000
	MIN	-10.00	-26.00
	MAX	19.00	18.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.0220
	P-VALUE Wilcoxon	.	0.0402
52W-開始時　国際勃起能スコア5	N	43.00	43.00
	Mean	-0.884	-0.698
	SD	4.871	8.605
	MEDIAN	0.000	0.000
	MIN	-14.00	-19.00
	MAX	17.00	19.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.8822
	P-VALUE Wilcoxon	.	0.6574

6. QOL比較　差の変化量（52W-開始時）境界型

		遅延型	即効型
52W-開始時　PF	N	13.00	19.00
	Mean	0.769	1.842
	SD	9.541	7.305
	MEDIAN	0.000	0.000
	MIN	-10.00	-5.00
	MAX	20.00	25.00
	NMISS	4	4
	P-VALUE STUDENT T-TEST	.	0.7211
	P-VALUE Wilcoxon	.	0.4110
52W-開始時　PR	N	13.00	18.00
	Mean	-10.10	0.347
	SD	28.013	14.925
	MEDIAN	0.000	0.000
	MIN	-100.00	-25.00
	MAX	6.25	50.00
	NMISS	4	5
	P-VALUE STUDENT T-TEST	.	0.1832
	P-VALUE Wilcoxon	.	0.4379
52W-開始時　BP	N	13.00	19.00
	Mean	6.077	-2.105
	SD	24.871	22.350
	MEDIAN	0.000	0.000
	MIN	-28.00	-48.00
	MAX	49.00	46.00
	NMISS	4	4

(Continued)

6. QOL比較　差の変化量（52W-開始時）境界型

		遅延型	即効型
52W-開始時　BP	P-VALUE STUDENT T-TEST	.	0.3350
	P-VALUE Wilcoxon	.	0.5635
52W-開始時　CH	N	14.00	18.00
	Mean	1.429	-1.667
	SD	9.841	16.332
	MEDIAN	1.250	0.000
	MIN	-20.00	-40.00
	MAX	20.00	20.00
	NMISS	3	5
	P-VALUE STUDENT T-TEST	.	0.5378
	P-VALUE Wilcoxon	.	0.6468
52W-開始時　VT	N	14.00	18.00
	Mean	-0.446	3.819
	SD	20.724	16.950
	MEDIAN	-3.125	3.125
	MIN	-43.75	-31.25
	MAX	31.25	37.50
	NMISS	3	5
	P-VALUE STUDENT T-TEST	.	0.5487
	P-VALUE Wilcoxon	.	0.6059
52W-開始時　SF	N	14.00	19.00
	Mean	-4.464	-6.579
	SD	27.125	21.798
	MEDIAN	0.000	0.000
	MIN	-62.50	-50.00

(Continued)

6. QOL比較　差の変化量（52W-開始時）境界型

		遅延型	即効型
52W-開始時　SF	MAX	50.00	37.50
	NMISS	3	4
	P-VALUE STUDENT T-TEST	.	0.5055
	P-VALUE Wilcoxon	.	0.7921
52W-開始時　RE	N	12.00	18.00
	Mean	-4.167	6.149
	SD	19.360	24.350
	MEDIAN	0.000	0.000
	MIN	-25.00	-25.00
	MAX	8.33	75.00
	NMISS	5	4
	P-VALUE STUDENT T-TEST	.	0.1773
	P-VALUE Wilcoxon	.	0.3609
52W-開始時　MH	N	14.00	18.00
	Mean	-7.500	-1.944
	SD	17.404	15.731
	MEDIAN	-5.000	0.000
	MIN	-40.00	-45.00
	MAX	25.00	20.00
	NMISS	3	5
	P-VALUE STUDENT T-TEST	.	0.3516
	P-VALUE Wilcoxon	.	0.3584

(Continued)

6. QOL比較　差の変化量（52W-開始時）境界型

		遅延型	即効型
52W-開始時　AMS(心理的)	N	17.00	23.00
	Mean	-2.647	-1.913
	SD	4.834	4.842
	MEDIAN	-1.000	0.000
	MIN	-14.00	-15.00
	MAX	2.00	4.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.6350
	P-VALUE Wilcoxon	.	0.4643
52W-開始時　AMS(身体的)	N	17.00	23.00
	Mean	-4.824	-1.783
	SD	8.734	8.453
	MEDIAN	-2.000	0.000
	MIN	-23.00	-21.00
	MAX	7.00	8.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.2744
	P-VALUE Wilcoxon	.	0.1920
52W-開始時　AMS(性機能)	N	17.00	23.00
	Mean	-3.471	-2.826
	SD	8.001	7.975
	MEDIAN	0.000	-1.000
	MIN	-21.00	-23.00
	MAX	4.00	8.00
	NMISS	0	0

(Continued)

6. QOL比較　差の変化量（52W-開始時）境界型

		遅延型	即効型
52W-開始時　AMS(性機能)	P-VALUE STUDENT T-TEST	.	0.8022
	P-VALUE Wilcoxon	.	0.8050
52W-開始時　国際前立腺症状スコア(I	N	17.00	23.00
	Mean	-2.647	-1.739
	SD	6.791	9.821
	MEDIAN	-3.000	-1.000
	MIN	-15.00	-24.00
	MAX	12.00	16.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.7415
	P-VALUE Wilcoxon	.	0.3793
52W-開始時　国際勃起能スコア5	N	17.00	23.00
	Mean	-3.824	-0.522
	SD	7.756	5.853
	MEDIAN	-4.000	-2.000
	MIN	-19.00	-14.00
	MAX	7.00	10.00
	NMISS	0	0
	P-VALUE STUDENT T-TEST	.	0.1328
	P-VALUE Wilcoxon	.	0.1769

研究成果の刊行に関する一覧表

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Guidelines

Clinical Practice Manual for Late-onset Hypogonadism Syndrome

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The Japanese Urological Association/Japanese Society for the Study of the Aging Male

Introduction

With the aging of the population, the quality of life (QOL) of middle-aged and elderly men has come into question and it has been taken up from an interdisciplinary standpoint in recent years.

Partial androgen deficiency of the aging male (PADAM) or late-onset hypogonadism (LOH) is a syndrome consisting of symptoms caused by partial deficiency of androgens, but the time of onset varies and the epidemiological status is unclear. Therefore, in Japan to date, this syndrome has been considered as a general phenomenon associated with aging, the medical authorities have not reacted and patients are not being treated.

In Western countries however, this phenomenon has attracted attention in relation to geriatrics and reproductive endocrinology since the 1980s. In 1998, the International Society for the Study of the Aging Male (ISSAM) was founded to conduct basic and clinical research, to provide postgraduate education and to engage in publicity activities for the enlightenment of the public. The social background is characterized by the appearance of a very rapidly aging society with longer average life spans. The importance of improving the health of the elderly and preventive medicine as government policy has increased. Improving the health of the elderly not only promotes self-reliance of the elderly but also increases the work force. A high QOL is also possible.

The main topic for healthcare in the 21st century is how to maintain the QOL of the elderly. In women, hormone replacement therapy (HRT) is widely applied internationally, but specific healthcare for elderly men appears to be limited to the widespread use of phosphodiesterase type 5 (PDE5) inhibitors to treat erectile dysfunction (ED). Although the delay in healthcare policies for elderly men is not a direct reason, a large gap has appeared between the average life spans of men and women in recent years and in Japan, men have a shorter life span than women by about seven years. In response to this sense of crisis, the World Health Organization (WHO) issued the Geneva Manifesto in 1997 and 'healthy aging for men' became an international movement. ISSAM was established in 1998 with the goal of 'aging male research on gender specific issues in male health'.

The first meeting of the society in Asia was held in Malaysia in 2001 and this topic was adopted on an international level from an early stage. The reason appeared to be strong economic and social concern that Asian countries with a current pyramid-type population distribution will become aging societies with a lower birth rate than in developing countries. Japan has already become an aging society with a low birth rate. In the national census (summary) in 2005, the elderly population of 65 years and older accounted for about 21% of the total population, the highest in the developed world.

In Japan, scientific research on the aging male started at about the same time as in the rest of Asia, and the Japanese Society for the Study of the Aging Male (JSSAM) was founded in November 2001 with Yoshiaki Kumamoto, professor emeritus of Sapporo Medical University, and Hajime Nawata, professor of Kyushu University as representative facilitators. The goal of this society is 'undertaking basic, clinical and social research and surveys on policies for the diagnosis, treatment and prevention of male-specific medical problems, and contributing widely to men's health by development, promotion and spread of proper healthcare'.

As mentioned above, the concept of research on the aging male is being promoted as 'healthy aging for men' but almost no actual treatment for such patients has been performed. When the JSSAM was established, so-called 'male climacteric symptoms' or 'male menopause' was popular in the media, and when such treatment was started, many patients mainly with a chief complaint of climacteric symptoms appeared in medical practice. These patients included many with psychiatric problems such as depression and considerable confusion arose in clinics and hospitals.

Based on this background, the Subcommittee on Endocrinology, Reproductive Function and Sexual Function of the Japanese Urological Association asked the Scientific Committee to prepare a clinical practice guideline, and a working group was organized to prepare the guideline by a collaborative team from the Japanese Urological Association and JSSAM after a review by the Board of Directors. In this clinical practice manual, the term 'late-onset hypogonadism (abbreviation: LOH)' syndrome was adopted as the term that best expresses this condition medically. In order to recommend standard procedures for diagnosis, treatment, prevention and monitoring of adverse reactions due to androgen replacement therapy (ART) and post-treatment assessments, a literature survey of clinical papers was performed, but since treatment of LOH Syndrome has just started, almost all papers had a low recommendation rank. Therefore, the name was changed to 'Clinical Practice *Manual* for Treatment of Late-onset Hypogonadism (LOH) Syndrome' ('Manual' hereinafter) instead of the initially planned 'clinical practice *guideline*'.

Care of LOH Syndrome is in its initial stages and such treatment requires careful consideration. Since many men visiting medical institutions at present complain of 'climacteric symptoms', measures must be taken to have this disease recognized in the mental health field. In the future, it will be necessary to establish evidence for treatment of LOH Syndrome from the broad perspective of promotion of 'healthy aging for men.' This 'Manual' is the first edition aimed at gathering evidence through future diagnosis and treatment of LOH and it is hoped that it will serve as a reference for routine medical practice.

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Table 1-1 Signs and symptoms of Late-onset Hypogonadism (LOH) Syndrome

1)	The easily recognized features of diminished sexual desire (libido) and erectile quality and frequency, particularly diminished nocturnal erections.
2)	Changes in mood with concomitant decreases in intellectual activity, cognitive functions, spatial orientation ability, fatigue, depressed mood and irritability.
3)	Sleep disturbances.
4)	Decrease in lean body mass with associated diminution in muscle volume and strength.
5)	Increase in visceral fat.
6)	Decrease in body hair and skin alterations.
7)	Decreased bone mineral density resulting in osteopenia, osteoporosis and increased risk of bone fractures.

Lunenfeld *et al. Aging Male* 2005; 8: 56–58.

[1] Definition of LOH

The term 'andropause' was used in the past for hypogonadism of the aging male, but internationally, the expressions androgen decline in the aging male (ADAM) or partial androgen deficiency of the aging male (PADAM) have been widely used to express a 'set of symptoms associated with androgen deficiencies due to aging.' In Japan, the PADAM concept has also become established.[1-3] However, the pathophysiology of men with the so-called 'climacteric symptoms' visiting medical institutions is complex. Patients in the stage of early male climacteric show a high percentage of stress-related psychosomatic symptoms and in many cases, androgen deficiency symptoms come to the fore in the mature stage after late male climacteric. Male climacteric shows a complex pathophysiology and it cannot be explained simply as a deficiency in androgens associated with aging in all cases. Since PADAM and male climacteric were considered to have the same meaning, it cannot be denied that this has resulted in confusion in medical practice.

In a joint recommendation by the International Society of Andrology (ISA), ISSAM and the European Association of Urology (EAU) in 2005, use of the term 'LOH' was recommended,[4-6] which was defined as 'A clinical and biochemical syndrome associated with advancing age and characterized by typical symptoms and a deficiency in serum testosterone levels. It may result in significant detriment in the quality of life and adversely affect the function of multiple organ systems'.[7] The key words in this definition are deficiency in androgen levels, aging, detriment in the quality of life and multiple organ dysfunction. The basic concept of 'healthy aging for men' is the prevention of reduction in organ functions caused by a deficiency in androgen levels associated with advancing age by androgen replacement.

In this Manual, the LOH Syndrome is used to accurately express this pathophysiology medically in keeping with this concept. Table 1-1 shows the signs and symptoms included in this syndrome based on the above recommendation.

[2] Diagnosis

LOH Syndrome starts with the evaluation of gonadal functions. Hormone testing is centered on testosterone blood levels and it is necessary to analyze test values based on an adequate understanding of biochemical diversity and characteristics. General laboratory tests and urological tests are useful in deciding the indications of ART as well as in the screening of the underlying diseases, and in simplifying the differential diagnosis of LOH Syndrome. LOH patients are often examined for unidentified complaints and questionnaires are essential in the differentiation from mental diseases, especially depression. Since relatively young men are also examined for this disorder, diagnosis without any predictions based on age is necessary.

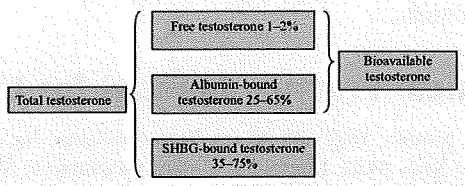


Fig. 1 Forms of testosterone. Vermeulen A. Diagnosis of partial androgen deficiency in the aging male. *Ann. Endocrinol.* 2003; 64: 109–114.

1 Hormone testing[8]

1) Gonadotropin and other pituitary hormones

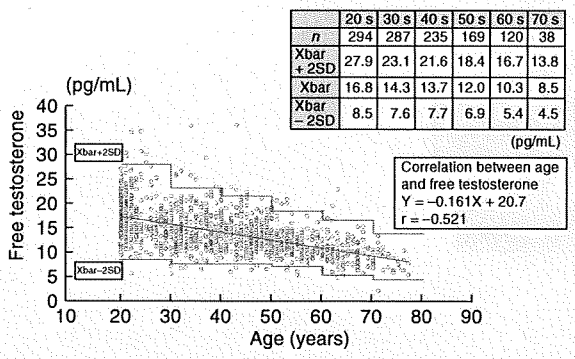
Sex hormones are controlled by precedence from the hypothalamus and pituitary gland and they can undergo changes caused by organic diseases such as tumors or inflammatory disease, aging or extrinsic factors such as drugs. The measurement of gonadotropin is useful in the differentiation between primary and secondary hypogonadism. Therefore, in diagnosis for LOH, it is necessary to measure pituitary hormones, the luteinizing hormone (LH) and the follicle-stimulating hormone (FSH). Prolactin (PRL) causes hypogonadism and it is recommended to measure PRL since hyperprolactinemia is caused by prolactin-producing tumors and by the adverse reactions of drugs such as sulpiride. Deficiencies in growth hormone (GH)/insulin-like growth factor (IGF-1) can explain reduced muscle strength, increased visceral fat and reduced bone density and their measurement is also useful.

2) Testosterone

The main androgen is the testosterone produced in the testes. However, the active testosterone in the blood is free testosterone, which makes up only 1–2% of total testosterone. Total testosterone consists of three fractions: the sex hormone binding globulin (SHBG)-bound testosterone, albumin-bound testosterone and free testosterone. Since albumin-bound testosterone can be easily separated from albumin, it is called bioavailable testosterone (BAT), which is biologically active, when combined with free testosterone (Fig. 1). SHBG however, is tightly bound to testosterone and this combination is biologically inactive. Since SHBG bound testosterone gradually increases with age, BAT is considered to show a relative decrease with no change in total testosterone. If total testosterone, SHBG and albumin are measured, it is possible to obtain calculated free testosterone and calculated BAT by such calculations (http://www.issam.ch/freetesto.htm).

3) Adrenal steroids

Because the adrenal androgens dehydroepiandrosterone (DHEA) and DHEA-sulfate (DHEA-S) gradually decrease with aging, they can serve as a senility indicator and might cause LOH signs and symptoms. Blood levels of cortisol basically show no changes throughout life, but



	20 s	30 s	40 s	50 s	60 s	70 s
n	294	287	235	169	120	38
Xbar + 2SD	27.9	23.1	21.6	18.4	16.7	13.8
Xbar	16.8	14.3	13.7	12.0	10.3	8.5
Xbar − 2SD	8.5	7.6	7.7	6.9	5.4	4.5

Fig. 2 Distribution of free testosterone with age.

they are known to be altered by stress, which makes these values useful in the differentiation of LOH and transient stress.

2 Standard values for ART indications

1) Overseas values

In the guidelines of the Consensus Committee of the Endocrine Society in the United States (2001),[9] the standard value for indication of ART is total testosterone of less than 2.0 ng/mL. For patients with values of 2.0–4.0 ng/mL, free testosterone and BAT are recommended as references. In the ISA, ISSAM and EAU recommendation of Lunenfeld *et al.* LOH standard value is a total testosterone of less than 8 nmol/L (2.31 ng/mL) and the normal value is not less than 12 nmol/L (3.46 ng/mL). Therefore, patients with values of greater than 8 and less than 12 nmol/L (2.31–3.46 ng/mL) are defined as borderline. In such patients, determination of calculated free testosterone is recommended and a diagnosis and treatment algorithm should be prepared.[7] According to the detailed policies of Nieschlag *et al.*,[10] total testosterone and SHBG are measured by a chemistry test using blood collected between 7 and 11 AM. Thus, the algorithm for diagnosis of LOH Syndrome overseas is based on total testosterone, not free testosterone.

2) Japanese values

From studies on healthy men in Japan however,[11] it was found that decreases in total testosterone with age are very slight, but free testosterone values decrease significantly with aging (Fig. 2). Total testosterone and free testosterone cannot be measured simultaneously for LOH Syndrome because of health insurance coverage. Therefore, the Working Committee on Clinical Practice Guidelines for Late-onset Hypogonadism recommends that free testosterone should be the diagnostic test for LOH Syndrome.

Free testosterone cannot be expressed uniformly as a mean value for the reason described previously. Therefore, the data in Figure 2 was used as the standard diagnostic criteria for LOH Syndrome and the normal lower limit was set at a mean–2SD value of 8.5 pg/mL for men in their twenties. Patients with values of greater than 8.5 pg/mL and less than 11.8 pg/mL, 70% of the mean value for men in their twenties (young adult mean: YAM) are recommended to be given ART as cases with a tendency toward low androgen levels (LOH borderline cases). The reason for applying the concept of the YAM percentage of the free testosterone value is that the mean values by age range only decrease to 80% from andropause through the mature stage, when LOH Syndrome occurs most frequently, using the YAM value of total testosterone. However, the YAM value of free testosterone shows a linear decrease with aging and drops to 50%, indicating that the effect of the decrease in the standard level with aging is more marked for free testosterone than for total testosterone. Even within the standard ranges (mean–2SD) of total testosterone and free testosterone, it is possible to detect an abnormal value with assessment using the YAM percentage. The YAM value is already applied in routine clinical practice for the evaluation of bone mineral density in osteoporosis based on evidence based medicine (EBM).[12]

The algorithm for diagnosis of LOH in Japan (Fig. 3) has been prepared for reference. Differences in the standard value of free testosterone in this Manual and the standard calculated free testosterone value for LOH recommended by ISA, ISSAM and EAU[7] are due to differences in the measurement and calculation methods and caution is required when making comparisons.[13]

3 Laboratory tests (Table 1-2)

1) General laboratory tests

There are currently no specific physical findings or test parameters for LOH Syndrome. At present, it is valid to use general parameters for excluding other serious diseases and prostate diseases and for assessment before treatment and during the course of treatment associated with ART. Table 1-2 shows the required minimum parameters for assessment as the essential parameters that can be measured routinely, and the optional values.

Androgens are known to act on erythrocyte production, glucose metabolism and lipids. In recent years, the metabolic syndrome based on visceral fat obesity has attracted attention and in consideration of the antiobesity effects of testosterone, LOH Syndrome might be complicated with the metabolic syndrome. Evaluation of the metabolic syndrome is performed using the BMI (height and weight) and the waist-hip ratio. Diagnostic criteria were published in April 2005 based on a consensus of eight societies including the Japanese Society of Internal Medicine.[14] A waist circumference of Japanese males of 85 cm or more, equivalent to a visceral fat area of 100 cm^2 or more on CT, was applied as the essential item in these diagnostic criteria.

2) Urological tests

A visual examination including the pudendal region is very important as an indicator of androgen deficiency of LOH.

1 Palpation of the testes and measurement of testicular volume

In palpation of the testes, epididymis, ductus deferens and spermatic cord are palpated in that order. The size and hardness or softness of the testes is especially important. Testicular volume is measured by a testicular ultrasound examination or a testicular volume meter.

2 Observation of body hair

It is important to observe changes in facial and pubic hair since they are often correlated with androgen concentration.

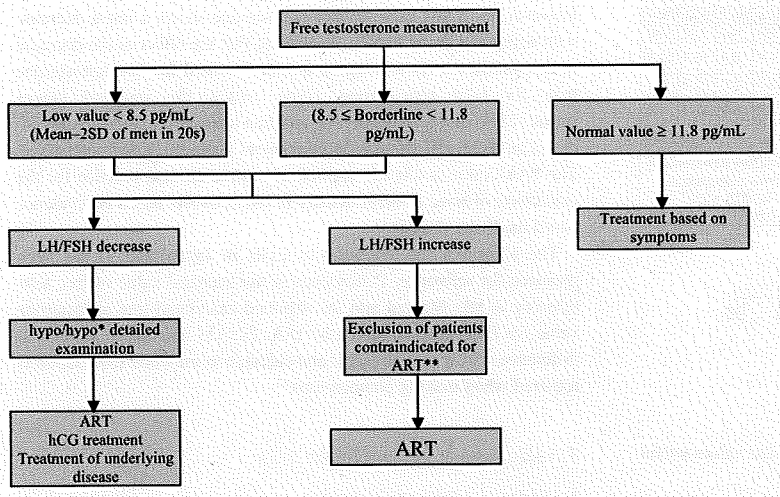
3 Evaluation of sexual function

(a) Sexual function is usually assessed by the International Index of Erectile Function (IIEF) or the simplified IIEF5. The results are useful in assessment of therapeutic effects.

(b) Nocturnal penile tumescence (NPT) and morning erection are simple and useful assessments of sexual function. The erectometer can also be used as a simplified method.

4 Prostate evaluation

(a) Evaluations of symptoms related to urination and voiding conditions are useful for differentiation from prostate dis-



*: Hypogonadotropic hypogonadism
**: Androgen replacement therapy

(Working Committee on Treatment Guidelines for Late-onset Hypogonadism)

Fig. 3 Algorithm of diagnosis of Late-onset Hypogonadism (LOH).

Table 1-2 Tests for Late-onset Hypogonadism (LOH)

Essential tests	
Physical findings	Height, weight, BMI, waist circumference (umbilical circumference), blood pressure, grip strength (both hands)
Examinations	Chest X-ray, ECG
Hematology	Especially hemoglobin, hematocrit, RBC count
Blood chemistry	Especially, TC, TG, HDL-C, LDL-C, GOT, GPT, ALP, γ-GTP, Ca, P
Urinalysis	Protein, glucose, occult blood
Glucose tolerance	FBS, HbA_{1c}
Tumor marker	PSA
Optional tests	
Bone mineral density	Dual energy X-ray absorptiometry (DEXA)
Body fat ratio	
Urological tests	
Physical tests	Testicular palpation, testicular volume measurement, pudendum (penis), body hair (facial hair, pubic hair), digital rectal examination of the prostate
Questionnaires	International Index of Erectile Function (IIEF) International Prostate Symptom Score (IPSS)

BMI, body mass index; DEXA, Dual energy X-ray absorptiometry; ECG, electrocardiogram; PSA, prostate specific antigen.

eases. The International Prostate Symptom Score (IPSS) is a diagnostic aid.

(b) A digital rectal examination of the prostate is important for diagnosis of prostatic hyperplasia and prostate cancer.

4 Questionnaires

1) Questionnaires used in LOH Syndrome diagnosis

Various symptoms are caused by reduced testosterone levels in the aging male, and questionnaires are widely used for screening. The most widely used questionnaire at present is the Aging males' symptoms (AMS) scale by Heinemann *et al.*[15,16] (Table 1-3). The self-rating questionnaire consists of five questions on psychological factors (questions 6–8, 11, 13), seven on physical factors (questions 1–5, 9, 10) and five on sexual function factors (questions 12, 14–17) for a total of 17 questions. Each question is answered in five grades: 'none', 'mild', 'moderate', 'severe' and 'extremely severe' and the grade is assigned one to five points. The AMS score was found to be effective for 116 men over the age of 40 and 992 German men over the age of 40 were tested for verification. It has now been translated into 14 languages and is useful in international comparisons of LOH symptoms.[17]

When this questionnaire was applied to urology department outpatients (without complaint for andropause), the overall severity was found to increase with aging, but it has often been reported that there is no clear correlation coefficient between the AMS score and blood levels of total testosterone.[18] No papers have appeared on the correlation with free testosterone to date and this point awaits further study. Since some questions show different nuances based on German culture such as Question 12 'Feeling that you have passed your peak' classified as a sexual factor, caution is required when using this questionnaire in Japan.

The Male Climacteric Symptom Scale by Kumamoto (MCS-K) (Table 1-4) is a questionnaire on male climacteric symptoms developed in Japan. In males with male climacteric symptoms, the total 'MCS-K' score and the AMS score show a significant correlation. However, this form has not been adequately validated for diagnosis and evaluation of LOH Syndrome and future studies are required.

2) Diagnosis of depression

The mental symptoms of LOH Syndrome are similar to those of depression and differentiation is difficult. As a mental disorder, depression is broadly classified into two types: major depressive disorders and dysthymic disorders. Diagnostic and Statistical Manual of Mental Disorders, the 4th Edition (DSM-IV), the diagnostic criteria of the American Psychiatric Association, is often used for diagnosis of depression, but structured interviews are recommended to increase the reliability of the results. For this reason, the Mini International Neuropsychiatric

Table 1-3 Aging males' symptoms (AMS) scale by Heinemann *et al.*

	Symptoms	None	Mild	Moderate	Severe	Extremely severe
	Points	1	2	3	4	5
1	Decline in your feeling of general well-being (general state of health, subjective feeling)	1	2	3	4	5
2	Joint pain and muscle ache (lower back pain, joint pain, pain in a limb, general back ache)	1	2	3	4	5
3	Excessive sweating (unexpected/sudden episodes of sweating, hot flushes independent of strain)	1	2	3	4	5
		1	2	3	4	5
4	Sleep problems (difficulty in falling asleep, difficulty in sleeping through, waking up early and feeling tired, poor sleep, sleeplessness)	1	2	3	4	5
		1	2	3	4	5
5	Increased need for sleep, often feeling tired	1	2	3	4	5
6	Irritability (feeling aggressive, easily upset about little things, moody)	1	2	3	4	5
7	Nervousness (inner tension, restlessness, feeling fidgety)	1	2	3	4	5
8	Anxiety (feeling panicky)	1	2	3	4	5
9	Physical exhaustion/lacking vitality (general decrease in performance, reduced activity, lacking interest in leisure activities, feeling of getting less done, of achieving less, of having to force oneself to undertake activities)	1	2	3	4	5
10	Decrease in muscular strength	1	2	3	4	5
11	Depressive mood (feeling down, sad, on the verge of tears, lack of drive, mood swings, feeling nothing is of any use)	1	2	3	4	5
12	Feeling that you have passed your peak	1	2	3	4	5
13	Feeling burnt out, having hit rock bottom	1	2	3	4	5
14	Decrease in beard growth	1	2	3	4	5
15	Decrease in ability/frequency to perform sexually	1	2	3	4	5
16	Decrease in number of morning erections	1	2	3	4	5
17	Decrease in sexual desire/libido (lacking pleasure in sex, lacking desire for sexual intercourse)	1	2	3	4	5

Level of severity: 17–26 points, none; 27–36 points, mild; 37–49 points, moderate; more than 50 points, severe.
(Draft Japanese translation: Department of Urology, Sapporo Medical University School of Medicine)

Interview (M.I.N.I.) is widely used.[19,20] The M.I.N.I. was developed for the application of DSM-IV in routine practice and is designed to permit simple application in a short time.

Procedures for structured interviews using M.I.N.I. for major depressive disorders are shown in Table 1-5. With this procedure, the form is read out directly and an explanation is added if the meaning is not clear so that accurate replies can be obtained. First, there are two questions in a colored square. If the answers to both questions are 'No', it is judged negative for major depressive disorder and if the answer to either question is 'Yes', the diagnosis proceeds to the final stage based on the instructions.

Major depressive disorders are the most common form of depression and show a prevalence of 5–6% of the general population (3–4% of men). The test application of this questionnaire in 92 first-visit outpatients with andropause in a total of nine medical institutions nationwide in 2004 resulted in the diagnosis of 44 people (47.8%) with major depressive disorders. In people in their sixties, major depressive disorders were diagnosed in only about 20%, but in those in their forties and fifties, the figure was about 60%. Therefore, it appears that in addition to major depressive disorders as a complication of LOH, many patients, especially middle-aged ones, visit outpatient clinics for andropause among patients with major depressive disorders that are not associated with LOH.

Procedures for structured interviews using M.I.N.I. for dysthymic disorders are shown in Table 1-6. When the diagnosis of 'Major depressive episode – Current' is made as noted at the top of the page, this diagnosis is not considered.

The prevalence of dysthymic disorders is 10% of patients with major depressive disorders in the general population, but it is higher in middle-aged and elderly men. When testosterone levels were compared among groups with major depressive disorders, dysthymic disorders or healthy individuals in elderly men 60 years of age or older, it was reported that only the group with dysthymic disorders showed low levels. When the fact that major depressive disorders were few in men in their sixties visiting outpatient clinics for andropause as described above is also taken into consideration, it appears possible that dysthymic disorders are more closely related to LOH than major depressive disorders. Therefore, when symptoms such as a dejected mood occur and the diagnostic criteria for major depressive disorders are not met, it is necessary to consider a diagnosis of dysthymic disorders.

3) Severity assessment of symptoms of depression

The forms used for assessment of the severity of depression and changes in the severity of depression are basically divided into self-rating scales and observer rating scales. The self-rating scales include the Self-rating for Depression Scale (SDS), Beck Depression Inventory (BDI) and Hospital Anxiety and Depression Scale (HAD).[21,22] The most common observer-rating scale is the Hamilton Depression Rating Scale

Table 1-4 Male Climacteric Symptom Scale by Kumamoto (MCS-K)

	Symptoms	Almost none	Moderate	Severe	Very severe
A: Psychological factors	1. General physical condition not good, irritable	1	2	3	4
	2. Have trouble sleeping (Insomnia)	1	2	3	4
	3. Feeling of anxiety, loneliness	1	2	3	4
	4. Often uneasy, depressed mood	1	2	3	4
B: Physiological factors	5. Hot flushes, light-headedness, excessive sweating	1	2	3	4
	6. Palpitations, shortness of breath, suffocating feeling	1	2	3	4
	7. Dizziness, nausea	1	2	3	4
	8. Tire easily (fatigue)	1	2	3	4
	9. Headache, head feels stuffy, neck feels stiff	1	2	3	4
	10. Lower back pain, joint pain in limbs	1	2	3	4
	11. Stiffness in limbs	1	2	3	4
	12. Numbness, tingling sensation, cold feeling in limbs	1	2	3	4
C: Sexual factors	13. Decrease in sexual desire	1	2	3	4
	14. Decrease in erectile power	1	2	3	4
	Symptoms	At least 2 or 3 times a fortnight	Once a week	Occasionally	Almost never
	15. Aware of morning erection	1	2	3	4
	Symptoms	At least 2 or 3 times a fortnight	1 or 2 times a month	Less than once a month	Almost never
	16. Frequency of sex	1	2	3	4
	Questions for reference Symptoms	Almost none	Moderate	Severe	Very severe
Urination factors	Voiding difficulties, long time needed for urination	1	2	3	4
	Often has to urinate at night	1	2	3	4
	Cannot wait for urinary sensation, leakage	1	2	3	4

(HAM-D). None of these can be used for diagnosis and they should be used on the condition that they are applied only for assessment of the depressed state at the time of the replies. They are most useful in assessing changes in the depressed state associated with the course of treatment.

A depressed state is often only found when definite stress factors are present (usually persists for less than six months) and such cases are not very serious (they do not meet the diagnostic criteria for major depressive disorders). This is called a transient depressed state. When clinical problems arise in such patients, they are diagnosed as 'adjustment disorders with depressed mood' in DSM-IV. The symptom scores described here are useful in the evaluation of the severity of subjective symptoms.

4) Evaluation of ADL

Activities of daily living (ADL) are an important indicator of the mental and physical health status of the elderly. The Tokyo Metropolitan Institute of Gerontology (TMIG) Index of Competence (Table 1-7) is useful for evaluating independent activity levels in the elderly living in the community.[23] The Index consists of three factors: material self-reliance (questions 1–5), intellectual activeness (questions 6–9) and social role (questions 10–13). There are a total of 13 questions (5, 4 and 4, respectively). This is considered useful in assessment of delayed symptoms of LOH.

[3] Treatment

1 Usefulness of androgen replacement therapy (ART)

Androgens have many important physiological activities in men and they have affects on the muscle, bone, central nervous system, prostate gland, bone marrow and sexual function.

1 Actions related to sexual function include maintenance of sexual desire, ejaculation and erectile action.
2 A relation with maintenance of cognitive power and emotion is suggested but the actual relation remains unclear.
3 Reported actions on the muscles include enhanced muscle strength[24] and increased muscle mass and muscle strength.[25]
4 Actions on the bone include promotion of osteogenesis, and inhibition of bone resorption. Part of the bone mass maintenance action of testosterone occurs via the action of estrogen converted in the body. Many reports[24,26–30] have given an increase in bone mineral density as an effect of ART on bone.
5 The action on erythrocyte production involves a stimulation effect on erythrocyte production. In clinical studies, it was reported that hematocrit increased 2.0–5.0% during ART, above the normal value of 6–25%.[27,30–35] However, no significant increase in hematocrit was found when testosterone was administered percutaneously.
6 The effects on lipids and body fat include a decrease in body fat due to ART.[24,26,33] Total cholesterol and LDL cholesterol tend to decrease.