Methods

- 本研究はMedical Data Vision Co., Ltd.(MDV)という日本国内のデータベースを用いたコホート研究となっている。
- プライマリアウトカムは時間に対する退院イベントの累積、セカンダリアウトカムは入院日数、入院コスト、身体機能の低下（ADLの1つ以上の項目の減少で定義）、他院への転院もしくは長期間ケア型の機関への転院とした。
- 対象期間（2016年4月1日-2019年3月31日）に入院及び退院をした65歳以上の患者が選ばれ、完全期間拘束群（full-restraint, 入院期間全体に渡り拘束されている患者）、非拘束群（全く拘束を受けていない患者）、部分期間拘束群（partial-restraint、上記の2群に属さない患者）に分けられた。

Results

TABLE 1 Demographic characteristics

Characteristic	Physical restraint relative to hospital stays							
	Total (n = 18,255)		Full-restraint (n = 3930)		Partial-restraint (n = 4321)		No-restraint (n = 10,004)	
	n	%	n	%	n	%	n	%
Age								
65–74	1080	5.9	206	5.2	210	4.9	664	6.6
75–84	5262	28.8	1156	29.4	1243	28.8	2863	28.6
85–94	10,008	54.8	2148	54.7	2447	56.6	5413	54.1
≥95	1905	10.4	420	10.7	421	9.7	1064	10.6
Sex								
Male	8985	49.2	2183	55.5	2318	53.6	4484	44.8
Female	9270	50.8	1747	44.5	2003	46.4	5520	55.2
Admission source								
Home	10,273	56.3	2242	57.0	2505	58.0	5526	55.2
Long-term care institution	7982	43.7	1688	43.0	1816	42.0	4478	44.8
Diagnosis								
Pneumonia	8261	45.3	1774	45.1	1858	43.0	4629	46.3
Aspiration pneumonia	9994	54.7	2156	54.9	2463	57.0	5375	53.7
Charlson comorbidity index								
0	5698	31.2	1235	31.4	1410	32.6	3053	30.5
1	6915	37.9	1493	38.0	1664	38.5	3758	37.6
2	3730	20.4	823	20.9	817	18.9	2090	20.9
≥3	1912	10.5	379	9.6	430	10.0	1103	11.0
Coma at admission assessed by the Japan Coma Scale								
Not comatose (0)	15,245	83.5	3328	84.7	3590	83.1	8327	83.2
Comatose (I or more)	3010	16.5	602	15.3	731	16.9	1677	16.8
Barthel index at admission								
0–39	13,371	73.2	2865	72.9	3166	73.3	7340	73.4
40–59	1249	6.8	289	7.4	242	5.6	718	7.2
60–99	627	3.4	122	3.1	99	2.3	406	4.1
100	659	3.6	104	2.6	222	5.1	333	3.3
NA	2349	12.9	550	14.0	592	13.7	1207	12.1
ICU stay at admission								
Without	17,362	95.1	3709	94.4	4050	93.7	9603	96.0
With	893	4.9	221	5.6	271	6.3	401	4.0
Use of urinary catheter and/or nasogastric tube at admission								
Without	15,055	82.5	3159	80.4	3415	79.0	8481	84.8
With	3200	17.5	771	19.6	906	21.0	1523	15.2
Use of mechanical ventilation at admission								
Without	17,995	98.6	3855	98.1	4229	97.9	9911	99.1
With	260	1.4	75	1.9	92	2.1	93	0.9
Type of dementia care benefit at admission								
Low	14,360	78.7	3195	81.3	3457	80.0	7708	77.0
High	3895	21.3	735	18.7	864	20.0	2296	23.0
Need help during bathing								
No need (moderate dementia)	918	5.0	150	3.8	269	6.2	499	5.0
Need help (severe dementia)	16,134	88.4	3488	88.8	3741	86.6	8905	89.0
NA	1203	6.6	292	7.4	311	7.2	600	6.0

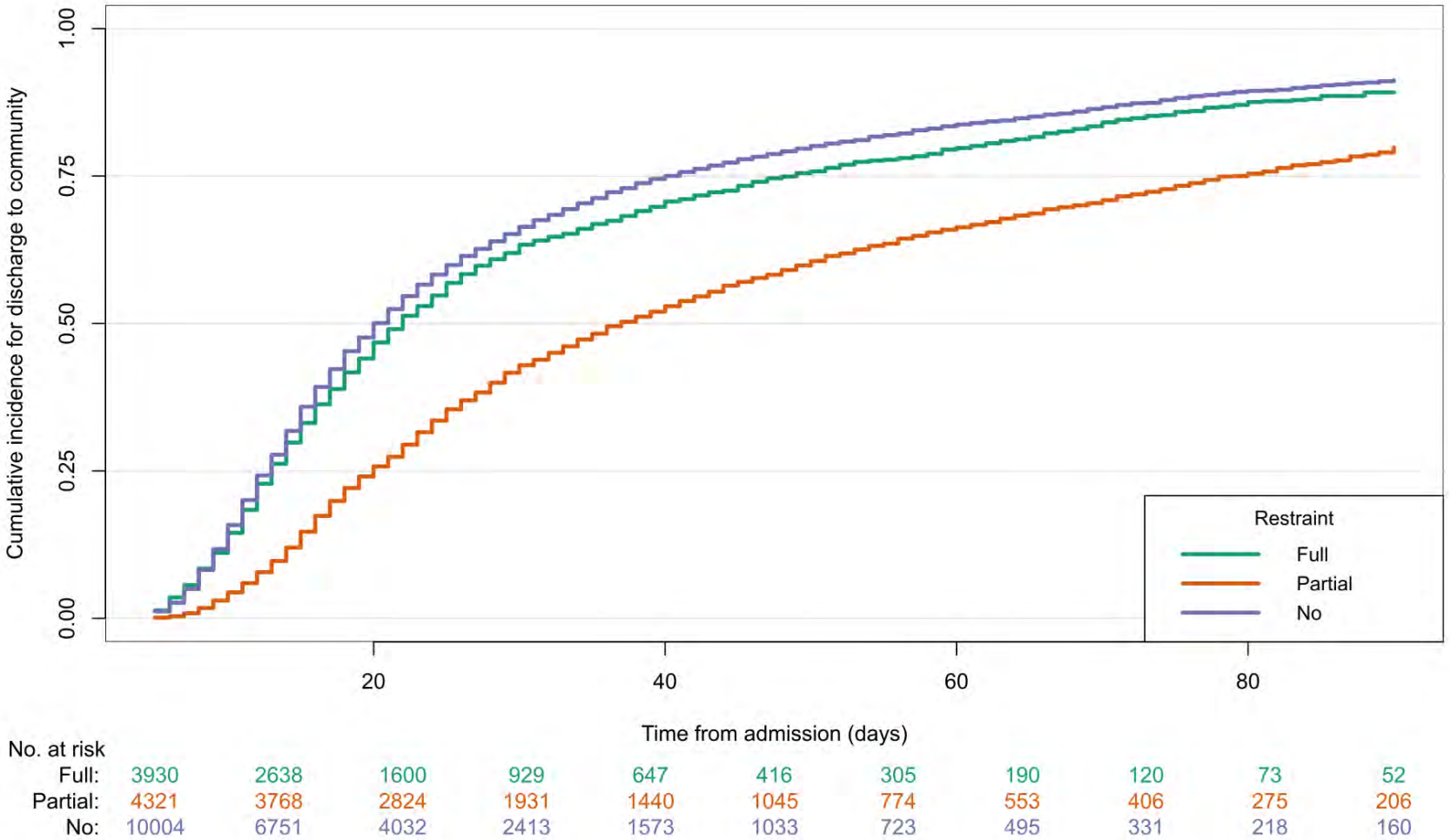

FIGURE 3 Cumulative incidence for discharge to community

TABLE 2 Association between physical restraint and secondary outcomes

Outcome	Full-restraint	Partial-restraint	No-restraint	Relative risk	
				Full- vs. no-restraint	Partial- vs. no-restraint
Length of stay, mean, days[a]	21.0	31.6	21.6	0.97 (0.94, 1.01)	1.46 (1.42, 1.51)*
Costs, mean, yen[a]	1,068,655	1,525,423	1,079,886	0.99 (0.96, 1.02)	1.41 (1.37, 1.45)*
Worse disability, %[b]	27.8	29.2	20.8	1.33 (1.22, 1.46)*	1.40 (1.29, 1.53)*
Institutionalisation, %[b,c]	4.5	5.0	4.2	1.07 (0.92, 1.23)	1.19 (1.04, 1.36)*
Transferal, %[b]	18.2	21.0	14.5	1.26 (1.15, 1.37)*	1.45 (1.34, 1.57)*
In-hospital mortality, %[b]	12.9	14.7	12.3	1.05 (0.94, 1.16)	1.19 (1.09, 1.31)*

*$p < .05$.

[a]Gamma regression model was used for length of stay and costs.

[b]Poisson regression model was used for binary outcomes.

[c]Institutionalisation was evaluated only for patients admitted from home.

Discussion

- 入院期間全体にわたる身体拘束が最も悪影響を及ぼすという仮説に反して、入院期間の一部の身体拘束が最も退院までにかかる日数が多い結果となり、それに続いて入院期間全体の身体拘束が悪影響をきたす結果となった。
- 1.入院期間全体で身体拘束をする必要があるハイリスクな患者を病態にかかわらずなるべく早く退院させたい病院が存在するということ
- 2.いくつかの病院では一定期間の入院ののち長期療養型の機関に移動することを入院時の条件としていること
- 3.服に装着するタイプのベッドセンサーシステムをつけているのみの患者が身体的拘束と定義されてしまっていること

Conclusion

- 65歳以上で認知症を患っている、肺炎で入院した患者に対して身体的拘束を行うことは退院へ至る割合を低下させ、退院時の身体的機能を低下させることがわかった。

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【 ORIGINAL ARTICLE 】

Conventional and Kampo Medicine Treatment for Mild-to-moderate COVID-19: A Multicenter, Retrospective, Observational Study by the Integrative Management in Japan for Epidemic Disease (IMJEDI Study-observation)

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Abstract:

Objective Patients in whom coronavirus disease 2019 (COVID-19) was suspected or confirmed between January 1, 2020, and October 31, 2021, were enrolled from Japanese hospitals in this multicenter, retrospective, observational study.

Methods Data on the treatment administered (including conventional and Kampo medicine) and changes in common cold-like symptoms (such as fever, cough, sputum, dyspnea, fatigue, and diarrhea) were collected from their medical records. The primary outcome was the number of days without a fever (with a body temperature <37°C). The secondary outcomes were symptomatic relief and the worsening of illness, defined as the presence of a condition requiring oxygen inhalation. The outcomes of patients treated with and without Kampo medicine were compared.

Patients We enrolled 962 patients, among whom 528 received conventional and Kampo treatment (Kampo group) and 434 received conventional treatment (non-Kampo group).

Results Overall, after adjusting for the staging of COVID-19 and risk factors, there were no significant between-group differences in the symptoms or number of days being afebrile. After performing propensity score matching and restricting the included cases to those with confirmed COVID-19 who did not receive steroid administration and initiated treatment within 4 days from the onset, the risk of illness worsening was significantly lower in the Kampo group than in the non-Kampo group (odds ratio=0.113, 95% confidence interval: 0.014-0.928, p=0.0424).

Conclusion Early Kampo treatment may suppress illness worsening risk in COVID-19 cases without steroid use. Further randomized controlled studies are needed to confirm the clinical benefit of Kampo medicine for COVID-19.

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