

Cozzolino P¹, D’Angiolella LS¹, Bosi E², Scavini S², Mantovani LG¹

¹ Research Centre of Public Health (CESP), University of Milan Bicocca, Monza Italy. ² Department of Internal Medicine, San Raffaele Hospital Scientific Institute, Milan, Italy

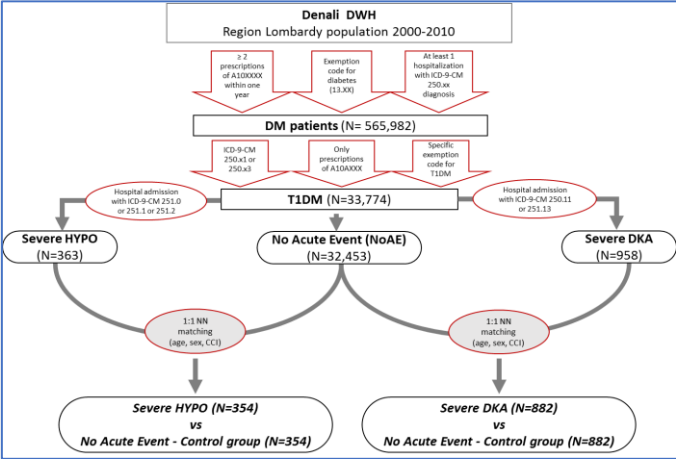
INTRODUCTION

Severe Hypoglycemia (HYPO) and Diabetes Ketoacidosis (DKA) are the two most serious acute complications of Type-1 Diabetes (T1DM). Severe HYPO and DKA are associated with an increased risk of death and place a heavy additional burden on health care systems. Using data from administrative databases, we assessed mortality and burden of severe HYPO and DKA in T1DM patients, compared to those without acute events (No AE) in Italy.

METHODS

Records were obtained for T1DM patients (N = 33,774) using DWH DENALI (Years 2000-2010), a data warehouse matching with probabilistic record-linkage data of about 10,000,000 individuals in the Lombardy Region, Italy. Severe HYPO and DKA events were identified using ICD-9-CM codes. Adopting the Italian National Health Service perspective, we only estimated direct costs. A 1:1 matching pair analysis to control for potential confounders was performed. Patients with acute events were compared with T1DM patients with no acute events (No AE), matched for age, gender and comorbidities (Figure 1).

Figure 1: Patients selection algorithm



RESULTS

A total of 882 T1DM patients in the DKA group and 354 T1DM patients in the severe HYPO group were included in the analysis and compared with 1,236 matched T1DM patients with No AE. Table 1 summarizes the baseline characteristics of study groups. Severe HYPO and DKA patients had a statistically significant higher risk of death compared to T1DM patients with No AE, however these differences were not statistically significant in the matched comparison analysis (p=0.4614 and 0.8510).

Table 1: Study population’s characteristics (after matching)

	DKA	No AE	Total	HYPO	No AE	Total
N	882	882	1,764	354	354	708
Age						
Mean (SD)	44.3 (25.4)	44.5 (24.0)	44.4 (24.7)	62.7 (19.1)	63.5 (17.9)	63.1 (18.5)
Median (IQR)	42.4 (22.9-68.4)	44.1 (24.6-65.5)	42.9 (24.1-67.0)	67.9 (49.6-77.0)	68.1 (55.1-76.2)	68.0 (52.4-76.7)
Sex – N (%)						
Female	400 (45.4)	390 (44.2)	790 (44.8)	177 (50.0)	184 (52.0)	361 (51.0)
Male	482 (54.7)	492 (55.8)	974 (55.2)	177 (50.0)	170 (48.0)	347 (49.0)
Charlson Comorbidity Index (CCI)						
CCI=0	566 (64.2)	564 (64.0)	1,130 (64.1)	125 (35.3)	125 (35.3)	250 (35.3)
CCI=1	98 (11.1)	104 (11.8)	202 (11.5)	58 (16.4)	59 (16.7)	117 (16.5)
CCI≥ 2	218 (24.7)	214 (24.3)	432 (24.5)	171 (48.3)	170 (48.0)	341 (48.2)

Costs observed in the severe HYPO patients during the years before and after the acute event were significantly higher than those observed in the DKA and No AE groups. The estimated average annual cost attributable to severe HYPO patients was 9,720 € per patient in the year before the AE, 10,978 € in the year after the AE, and 7,659 €, 2 years after the AE (Table 2). Inpatient costs was the major source of expenditure before the AE and in the subsequent years.

Table 2: Mean cost share by type per patient/year: DKA and HYPO vs. matched control population

	HYPO			No AE for HYPO			DKA			No AE for DKA		
	Inpatient	Outpatient	Drugs	Inpatient	Outpatient	Drugs	Inpatient	Outpatient	Drugs	Inpatient	Outpatient	Drugs
Year-1	€ 6,211.08	€ 1,982.88	€ 1.526.04	€ 488.22	€ 230.70	€ 355.16	€ 3,157.56	€ 992.38	€ 867.08	€ 323.24	€ 152.15	€ 177.62
Year+1	€ 7,234.50	€ 2,206.58	€ 1.536.92	€ 993.38	€ 410.84	€ 641.82	€ 7,516.87	€ 1,275.09	€ 1,491.04	€ 424.26	€ 233.82	€ 399.92
Year+2	€ 3,768.23	€ 2,213.45	€ 1.669.66	€ 744.79	€ 679.75	€ 673.46	€ 2,824.50	€ 1,205.12	€ 1,350.38	€ 252.56	€ 274.56	€ 352.88
Year+3	€ 4,423.91	€ 2,320.47	€ 1.594.28	€ 1,377.81	€ 692.90	€ 594.30	€ 2,968.29	€ 1,291.29	€ 1,330.42	€ 200.11	€ 252.41	€ 305.47
Year+4	€ 3,480.84	€ 2,911.25	€ 1.526.82	€ 1,549.04	€ 625.63	€ 557.33	€ 2,770.12	€ 1,341.44	€ 1,341.44	€ 303.75	€ 316.53	€ 363.71
Year+5	€ 3,712.12	€ 2,119.15	€ 1,376.73	€ 1,404.90	€ 178.00	€ 536.11	€ 3,520.52	€ 1,445.59	€ 1,271.12	€ 196.80	€ 300.00	€ 304.00

CONCLUSION

In patients with T1DM severe HYPO but not DKA is associated with increased healthcare resources utilization, mainly because of hospitalizations, significantly contributing to the high costs of diabetes care in these patients.