Post-trial monitoring of a randomised controlled trial of intensive glycaemic control in type 2 diabetes extended from 10 years to 24 years (UKPDS 91)

一、研究摘要

在臨床試驗結束後共 24 年的追蹤期間，積極血糖控制組有顯著較低的心肌梗塞風險與死亡率。

二、研究設計 **(study design)**

甲、試驗設計

觀察性追蹤研究(observational trial)。

乙、納入條件 **(inclusion criteria)**

- 英國糖尿病前瞻性(UKPDS)研究結束後之病人

丙、排除條件 **(exclusion criteria)**

- 病人無法或不願意後續追蹤。

三、試驗指標

甲、主要試驗指標 **(primary endpoint)**

Any diabetes-related endpoint, diabetes-related death, death from any cause, myocardial infarction, stroke, peripheral vascular disease, and microvascular disease。

乙、次要試驗指標 **(secondary endpoint)**

Not available。

四、介入與對照

甲、介入 **(intervention)**組後續追蹤

積極血糖控制組，使用 sulphonylurea 或是 insulin，體重過重者使用 metfomin，目標 FPG<6 mmol/L，並於試驗結束後繼續追蹤。

乙、對照 **(comparator)**組後續追蹤

傳統治療組，使用飲食介入，the aim was the best achievable FPG with diet alone; drugs were added only if there were hyperglycaemic symptoms or FPG greater than 15 mmol/L。試驗結束後繼續追蹤。

五、受試者概述

甲、人數 **(number of enrollees)**

1525。

乙、追蹤時間 **(duration of follow-up)**

14 年。

丙、平均年齡 **(mean age)**

Baseline: 50.2 歲。於追蹤結束 2021/9 平均為 79.9 歲

丁、女性比例 **(percentage female)**

41.3%

戊、併用治療 **(concomitant medications)**

無

六、主要發現

在臨床試驗結束後共 24 年的追蹤期間，積極血糖控制組有顯著較低的心肌梗塞風險與死亡率。此結論顯示，對於初診斷糖尿病的病人進行積極血糖控制，可減少將近終身糖尿病相關併發症發生的風險。

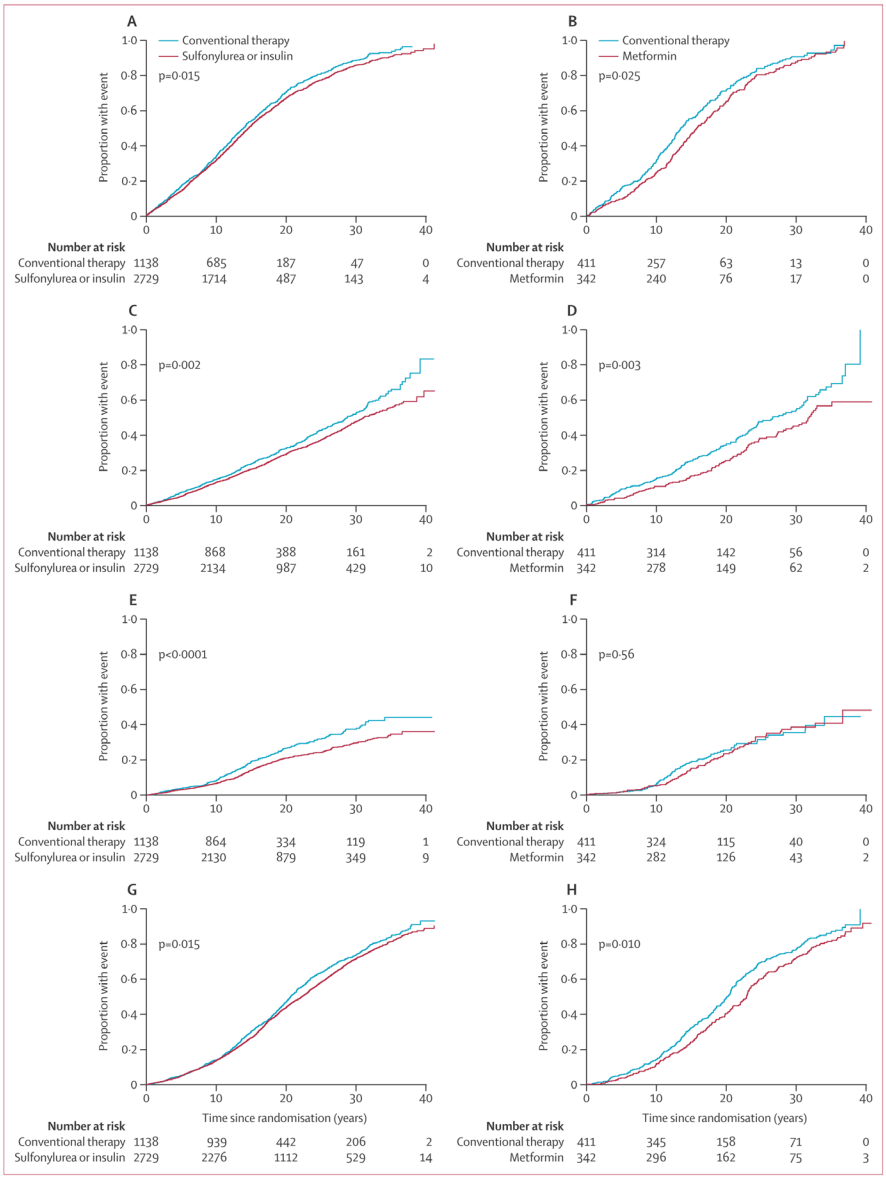

Figure 2: **Kaplan–Meier curves for four prespecified aggregate clinical outcomes**
The proportions of the UK Prospective Diabetes Study participants who had any diabetes-related endpoint (A–B), myocardial infarction (C–D), microvascular disease (E–F), or who died from any cause (G–H) are shown for the sulfonylurea or insulin group and for the metformin group, respectively vs their corresponding conventional therapy groups. Plots show cumulative incidence with numbers at risk at 10-year intervals from baseline, truncated at 40 years as so few participants remained at risk. Log-rank p values are shown for the entirety of follow-up. Kaplan–Meier curves for the other three prespecified aggregate clinical outcomes are summarised in the appendix (p 7).

	Participants with clinical outcome		Absolute risk		24-year post-trial follow-up		10-year post-trial follow-up	
	Intensive therapy	Conventional therapy	Intensive therapy	Conventional therapy	Relative risk for intensive therapy regimen (95% CI)	p value	Relative risk for intensive therapy regimen (95% CI)	p value
Sulfonylurea or insulin group								
Any diabetes-related endpoint	1816/2729 (66·5%)	792/1138 (69·6%)	50·4	54·9	0·90 (0·83–0·98)	0·015	0·91 (0·83–0·99)	0·040
Diabetes-related death	908/2729 (33·3%)	424/1138 (37·3%)	17·4	20·0	0·84 (0·75–0·94)	0·003	0·83 (0·73–0·96)	0·013
Death from any cause	1793/2729 (65·7%)	778/1138 (68·4%)	34·1	36.7	0·90 (0·83–0·98)	0·015	0·87 (0·79–0·96)	0·007
Myocardial infarction	897/2729 (32·9%)	422/1138 (37·1%)	18·4	21·7	0·83 (0·74–0·94)	0·002	0·85 (0·74–0·97)	0·015
Stroke	343/2729 (12·6%)	142/1138 (12·5%)	6·8	7·0	0·95 (0·78–1·16)	0·64	0·91 (0·73–1·13)	0·39
Peripheral vascular disease	118/2729 (4·3%)	55/1138 (4·8%)	2·3	2·7	0·83 (0·61–1·15)	0·27	0·82 (0·56–1·19)	0·29
Microvascular disease	497/2729 (18·2%)	261/1138 (22·9%)	10·7	14·2	0·74 (0·64–0·86)	<0·0001	0·76 (0·64–0·89)	0·001
Metformin group								
Any diabetes-related endpoint	245/342 (71·6%)	293/411 (71·3%)	49·6	56·2	0·82 (0·69–0·98)	0·025	0·79 (0·66–0·95)	0·013
Diabetes-related death	128/342 (37·4%)	168/411 (40·9%)	18·1	21.9	0·75 (0·60–0·95)	0·016	0·70 (0·53–0·92)	0·015
Death from any cause	243/342 (71·1%)	301/411 (73·2%)	34·4	49.3	0·80 (0·68–0·95)	0·010	0·73 (0·59–0·89)	0·002
Myocardial infarction	114/342 (33·3%)	164/411 (39·9%)	17·3	23·4	0·69 (0·54–0·88)	0·003	0·67 (0·51–0·89)	0·005
Stroke	46/342 (13·5%)	51/411 (12·4%)	6·7	7·0	0·88 (0·59–1·31)	0·53	0·80 (0·50–1·27)	0·35
Peripheral vascular disease	17/342 (5·0%)	30/411 (7·3%)	2·5	4·1	0·55 (0·31–1·01)	0·053	0·63 (0·32–1·27)	0·19
Microvascular disease	79/342 (23·1%)	88/411 (21·4%)	12·7	13·2	0·91 (0·67–1·24)	0·56	0·84 (0·60–1·17)	0·31

Data are n/N (%), unless otherwise specified. Absolute risk is the number of events per 1000 patient-years. Relative risk was estimated from hazard ratios calculated from proportional hazards modelling. p values were calculated using the log-rank test.

***Table*: Clinical outcomes from baseline for participants after up to 24-year post-trial follow-up, and after up to 10-year post-trial follow-up, as previously reported[4]**

七、參考資料

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