Mais diable ! Que fait le NEJM avec les statistiques dans ses abstracts !

Michel Cucherat

AVANT ! LE NEJM FAISAIT UNE INTERPRÉTATION CORRECTE DES STATISTIQUES

Tout le monde sait que la signification statistique c'est $p<0.05$!

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Table 2. Main Fatal and Nonfatal End Points in the Intention-to-Treat Population.

End Point	Rate per 1000 Patient-Yr (No. of Events)		Unadjusted Hazard Ratio (95% CI)	P Value
	Active	Placebo		
	no. (%)			
Stroke				
Fatal or nonfatal	12.4 (51)	17.7 (69)	0.70 (0.49–1.01)	0.06
Death from stroke	6.5 (27)	10.7 (42)	0.61 (0.38–0.99)	0.046
Death				
From any cause	47.2 (196)	59.6 (235)	0.79 (0.65–0.95)	0.02
From noncardiovascular or unknown causes	23.4 (97)	28.9 (114)	0.81 (0.62–1.06)	0.12
From cardiovascular cause	23.9 (99)	30.7 (121)	0.77 (0.60–1.01)	0.06
From cardiac cause*	6.0 (25)	8.4 (33)	0.71 (0.42–1.19)	0.19
From heart failure	1.5 (6)	3.0 (12)	0.48 (0.18–1.28)	0.14

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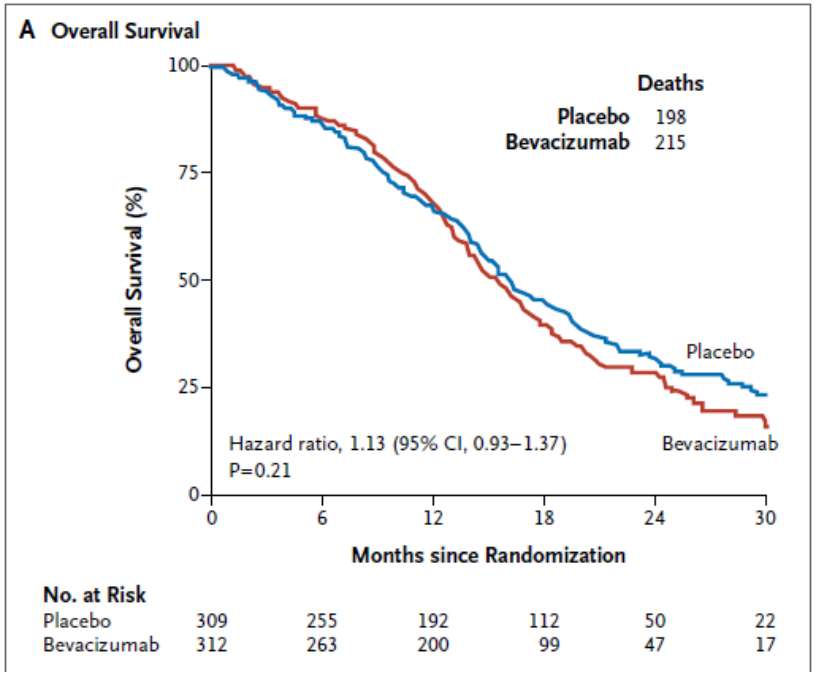
CONCLUSIONS

The results provide evidence that antihypertensive treatment with indapamide (sustained release), with or without perindopril, in persons 80 years of age or older is beneficial. (ClinicalTrials.gov number, NCT00122811.)

the placebo group. To control for type I errors in testing for the coprimary end points by means of the log-rank test,[21] the threshold for statistical significance was set at a two-sided P value of 0.046 for overall survival and 0.004 for progression-free survival. The enrollment goal



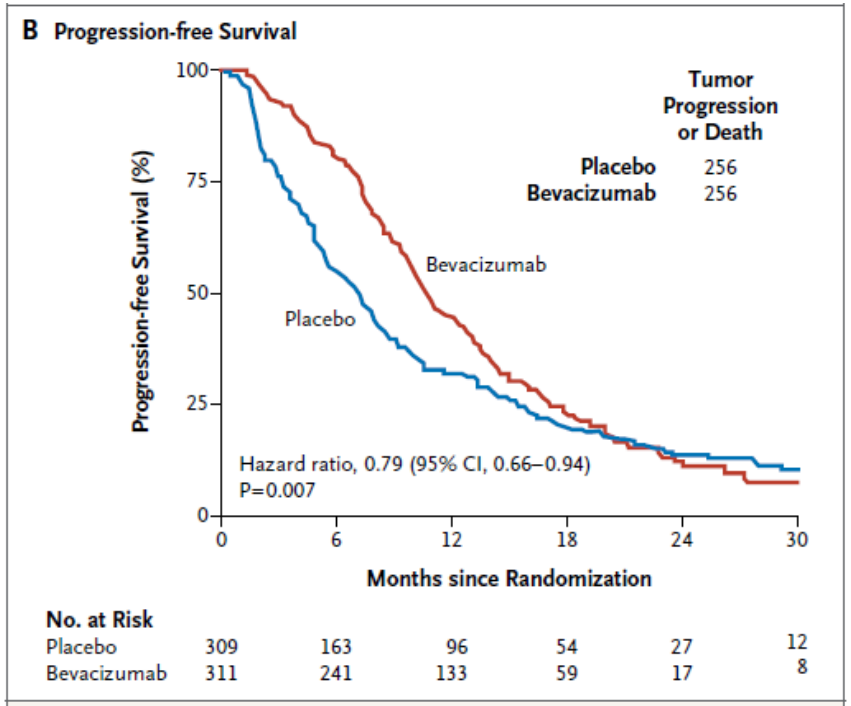


Figure 2. Primary End Points, According to Study Group.
The median rates of overall survival were similar in the bevacizumab and placebo groups (Panel A). The median rate of progression-free survival was higher in the bevacizumab group than in the placebo group but did not reach the prespecified threshold for significance (P<0.004) (Panel B).

CONCLUSIONS

First-line use of bevacizumab did not improve overall survival in patients with newly diagnosed glioblastoma. Progression-free survival was prolonged but did not reach the prespecified improvement target. (Funded by the National Cancer Institute; ClinicalTrials.gov number, NCT00884741.)

At the time of the interim analysis of overall survival, 173 patients in the continuous lenalidomide–dexamethasone group, 192 in the group that received 18 cycles of lenalidomide–dexamethasone, and 209 in the MPT group had died. The overall survival rates at 3 years were 70% with continuous lenalidomide–dexamethasone, 66% with 18 cycles of lenalidomide–dexamethasone, and 62% with MPT; the overall survival rates at 4 years were 59%, 56%, and 51%, respectively. Although the difference in overall survival did not cross the prespecified superiority boundary ($P<0.0096$), continuous lenalidomide–dexamethasone reduced the risk of death, as compared with MPT (hazard ratio, 0.78; 95% CI, 0.64 to 0.96; $P=0.02$) (Fig. 1B).

RÉCEMMENT LE NEJM FAIT N'IMPORTE QUOI AVEC LES STAT !

RESULTS

The primary outcome was not affected by ACE inhibitor therapy, statin therapy, or the combination of the two. The use of an ACE inhibitor was associated with a lower incidence of microalbuminuria than the use of placebo; in the context of negative findings for the primary outcome and statistical analysis plan, this lower incidence was not considered significant (hazard ratio, 0.57; 95% confidence interval, 0.35 to 0.94).

RESULTS

The median progression-free survival was significantly longer with osimertinib than with standard EGFR-TKIs (18.9 months vs. 10.2 months; hazard ratio for disease progression or death, 0.46; 95% confidence interval [CI], 0.37 to 0.57; P<0.001). The objective response rate was similar in the two groups: 80% with osimertinib and 76% with standard EGFR-TKIs (odds ratio, 1.27; 95% CI, 0.85 to 1.90; P=0.24). The median duration of response was 17.2 months (95% CI, 13.8 to 22.0) with osimertinib versus 8.5 months (95% CI, 7.3 to 9.8) with standard EGFR-TKIs. Data on overall survival were immature at the interim analysis (25% maturity). The survival rate at 18 months was 83% (95% CI, 78 to 87) with osimertinib and 71% (95% CI, 65 to 76) with standard EGFR-TKIs (hazard ratio for death, 0.63; 95% CI, 0.45 to 0.88; P=0.007 [nonsignificant in the interim analysis]). Adverse events of grade 3 or higher were less frequent with osimertinib than with standard EGFR-TKIs (34% vs. 45%).

RESULTS

Of 1634 fetuses that underwent randomization, 1566 were born alive before 30 weeks of gestation; of these, 782 were assigned to immediate cord clamping and 784 to delayed cord clamping. The median time between delivery and cord clamping was 5 seconds and 60 seconds in the respective groups. Complete data on the primary outcome were available for 1497 infants (95.6%). There was no significant difference in the incidence of the primary outcome between infants assigned to delayed clamping (37.0%) and those assigned to immediate clamping (37.2%) (relative risk, 1.00; 95% confidence interval, 0.88 to 1.13; P=0.96). The mortality was 6.4% in the delayed-clamping group and 9.0% in the immediate-clamping group (P=0.03 in unadjusted analyses; P=0.39 after post hoc adjustment for multiple secondary outcomes). There were no significant differences between the two groups in the incidences of chronic lung disease or other major morbidities.

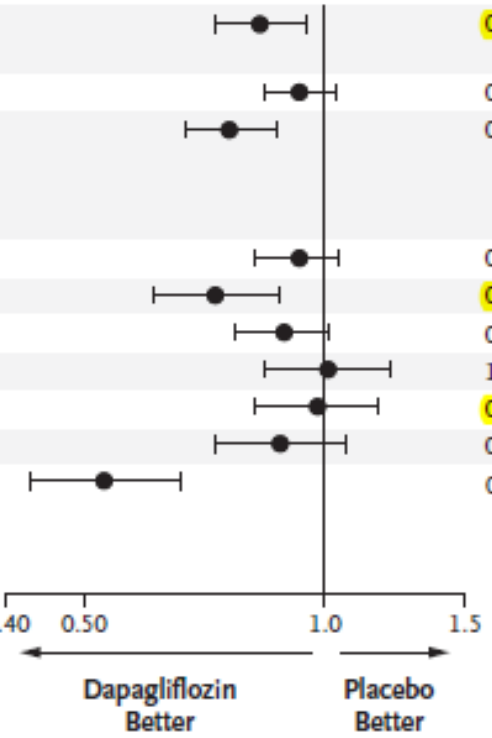
these two groups. There were 313 deaths (3.4%) in the rivaroxaban-plus-aspirin group as compared with 378 (4.1%) in the aspirin-alone group (hazard ratio, 0.82; 95% CI, 0.71 to 0.96; P=0.01; threshold P value for significance, 0.0025). The primary outcome

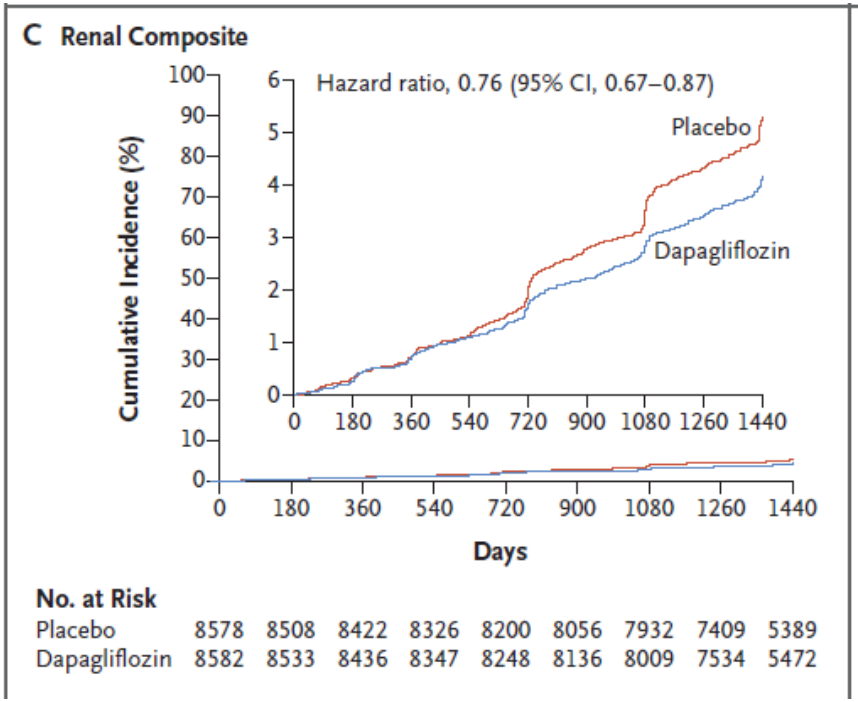
RESULTS

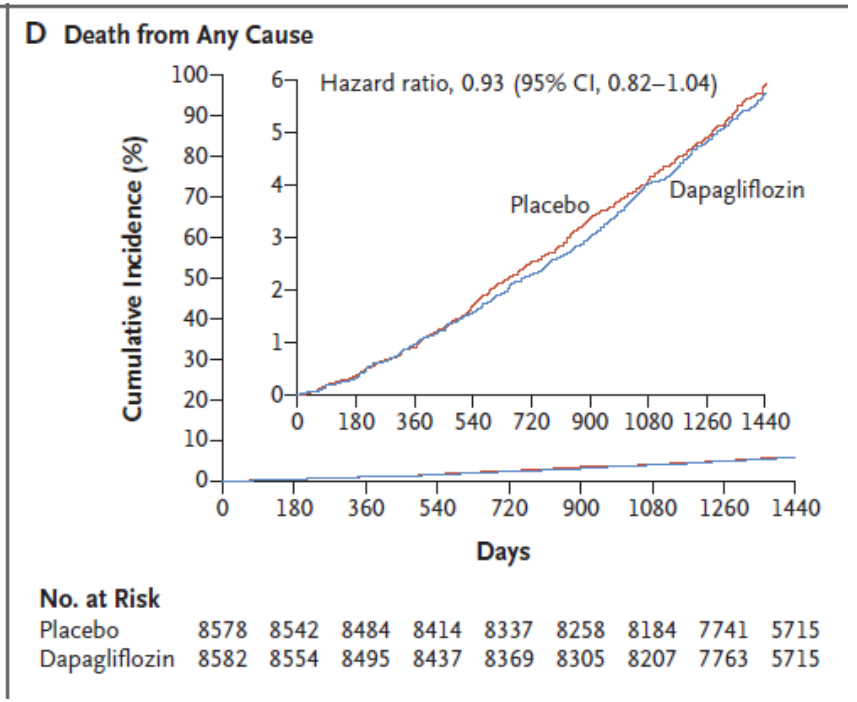
A total of 1096 patients were assigned to receive nivolumab plus ipilimumab (550 patients) or sunitinib (546 patients); 425 and 422, respectively, had intermediate or poor risk. At a median follow-up of 25.2 months in intermediate- and poor-risk patients, the 18-month overall survival rate was 75% (95% confidence interval [CI], 70 to 78) with nivolumab plus ipilimumab and 60% (95% CI, 55 to 65) with sunitinib; the median overall survival was not reached with nivolumab plus ipilimumab versus 26.0 months with sunitinib (hazard ratio for death, 0.63; P<0.001). The objective response rate was 42% versus 27% (P<0.001), and the complete response rate was 9% versus 1%. The median progression-free survival was 11.6 months and 8.4 months, respectively (hazard ratio for disease progression or death, 0.82; P=0.03, not significant per the prespecified 0.009 threshold). Treatment-related adverse events occurred

or sunitinib (50 mg) orally once daily for 4 weeks (6-week cycle). The coprimary end points were overall survival (alpha level, 0.04), objective response rate (alpha level, 0.001), and progression-free survival (alpha level, 0.009) among patients with intermediate or poor prognostic risk.

Outcome	Dapagliflozin (N=8582) no. (%)	Dapagliflozin (N=8582) rate/1000 patient-yr	Placebo (N=8578) no. (%)	Placebo (N=8578) rate/1000 patient-yr	Hazard Ratio (95% CI)	P Value
Cardiovascular death or hospitalization for heart failure	417 (4.9)	12.2	496 (5.8)	14.7	0.83 (0.73–0.95)	0.005
MACE	756 (8.8)	22.6	803 (9.4)	24.2	0.93 (0.84–1.03)	0.17
≥40% decrease in eGFR to <60 ml/min/1.73 m^2, ESRD, or death from renal or cardiovascular cause	370 (4.3)	10.8	480 (5.6)	14.1	0.76 (0.67–0.87)	
Death from any cause	529 (6.2)	15.1	570 (6.6)	16.4	0.93 (0.82–1.04)	
Hospitalization for heart failure	212 (2.5)	6.2	286 (3.3)	8.5	0.73 (0.61–0.88)	
Myocardial infarction	393 (4.6)	11.7	441 (5.1)	13.2	0.89 (0.77–1.01)	
Ischemic stroke	235 (2.7)	6.9	231 (2.7)	6.8	1.01 (0.84–1.21)	
Death from cardiovascular cause	245 (2.9)	7.0	249 (2.9)	7.1	0.98 (0.82–1.17)	
Death from noncardiovascular cause	211 (2.5)	6.0	238 (2.8)	6.8	0.88 (0.73–1.06)	
≥40% decrease in eGFR to <60 ml/min/1.73 m^2, ESRD, or death from renal cause	127 (1.5)	3.7	238 (2.8)	7.0	0.53 (0.43–0.66)	




C Renal Composite
Hazard ratio, 0.76 (95% CI, 0.67–0.87)
Placebo
Dapagliflozin
Cumulative Incidence (%)
Days
No. at Risk
Placebo 8578 8508 8422 8326 8200 8056 7932 7409 5389
Dapagliflozin 8582 8533 8436 8347 8248 8136 8009 7534 5472


D Death from Any Cause
Hazard ratio, 0.93 (95% CI, 0.82–1.04)
Placebo
Dapagliflozin
Cumulative Incidence (%)
Days
No. at Risk
Placebo 8578 8542 8484 8414 8337 8258 8184 7741 5715
Dapagliflozin 8582 8554 8495 8437 8369 8305 8207 7763 5715

EN FAIT, SOYONS SÉRIEUX !

3 premiers exemples → spins

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3

Les autres exemples (4 à 10)

- Abstracts vertueux du NEJM
- L'interprétation des p values est donnée explicitement
- La signification statistique n'est plus $p<0.05$
  - Surtout avec les méthodes modernes

There were two categories of secondary end points. For key secondary end points, testing for superiority was performed in a prespecified hierarchical order with the use of a gatekeeping method to control for multiple comparisons; P values are presented with claims of significance. For other secondary end points, analyses were performed without correction for multiple comparisons; hazard ratios and 95% confidence intervals are presented without P values or claims of significance, and inferences drawn from these 95% confidence intervals may not be reproducible.