A MULTI-METHOD QUALITY IMPROVEMENT INTERVENTION FAILS TO IMPROVE CLINICAL OUTCOMES IN CKD PATIENTS IN A CLUSTER-RANDOMIZED CLINICAL TRIAL (MAURO study).

Daniela Leonardis[1], Francesca Mallamaci[2], Giovanni Tripepi[1], Graziella D'Arrigo[1], Maurizio Postorino[2], Giuseppe Enia[2], Carmine Zoccali[2] on behalf of MAURO Working Group

[1] CNR –IFC/IBIM Clinical Epidemiology and Physiopathology of Renal Diseases and Hypertension - Reggio Calabria – Italy
[2] Nephrology, Dialysis and Transplantation Unit - BMM Hospital - Reggio Calabria - Italy.

Objectives:

The Multiple intervention and AUdit in Renal diseases to Optimize care (MAURO) is a cluster randomized trial (NCT00566033) aimed at assessing whether a multi-method quality improvement intervention is more effective than a less intensive intervention (control arm) in order to improve clinical outcomes and adherence to a series of relevant quality indicators in patients with chronic kidney disease (CKD)[1]. The intensive intervention added periodic knowledge refreshing, telephone and e-mail contacts and audits to baseline education on CKD guidelines.

Methods:

Seven hundred and fifty nine patients (CKD stages 2-5) were enrolled in 22 Nephrology Units Southern Italy. Eleven centers were randomized to the active arm (410 patients) while the remaining 11 centers were randomized to the control arm (349 patients). Study outcomes included a composite end-point (eGFR reduction $\geq$30%, dialysis and transplantation, cardio/cerebrovascular events and all cause death). Additional study outcomes pertained the control of hypertension, proteinuria, dyslipidemia, anemia and CKD-BMD (bone mineral disease) parameters.

Results:

During the follow-up (35 months), the incidence rate of the composite endpoint was almost identical (p = 0.49) in the two study arms (19 versus 18 events/100 person-years), and similar results were observed in separate analyses for renal events (p = 0.83), CV events (p = 0.44) and survival (p=0.78) (Figure). The control of hypertension, proteinuria, cholesterol and serum phosphate improved equally in the two study arms in longitudinal analysis by Mixed Linear Modelling (MLM) in patients out of target at enrollment (Table). In both groups the progression rate of CKD was identical to that achieved in clinical trials testing ACE inhibitors in the Italian populations (REIN and AIPRI studies, data not shown).

Figure
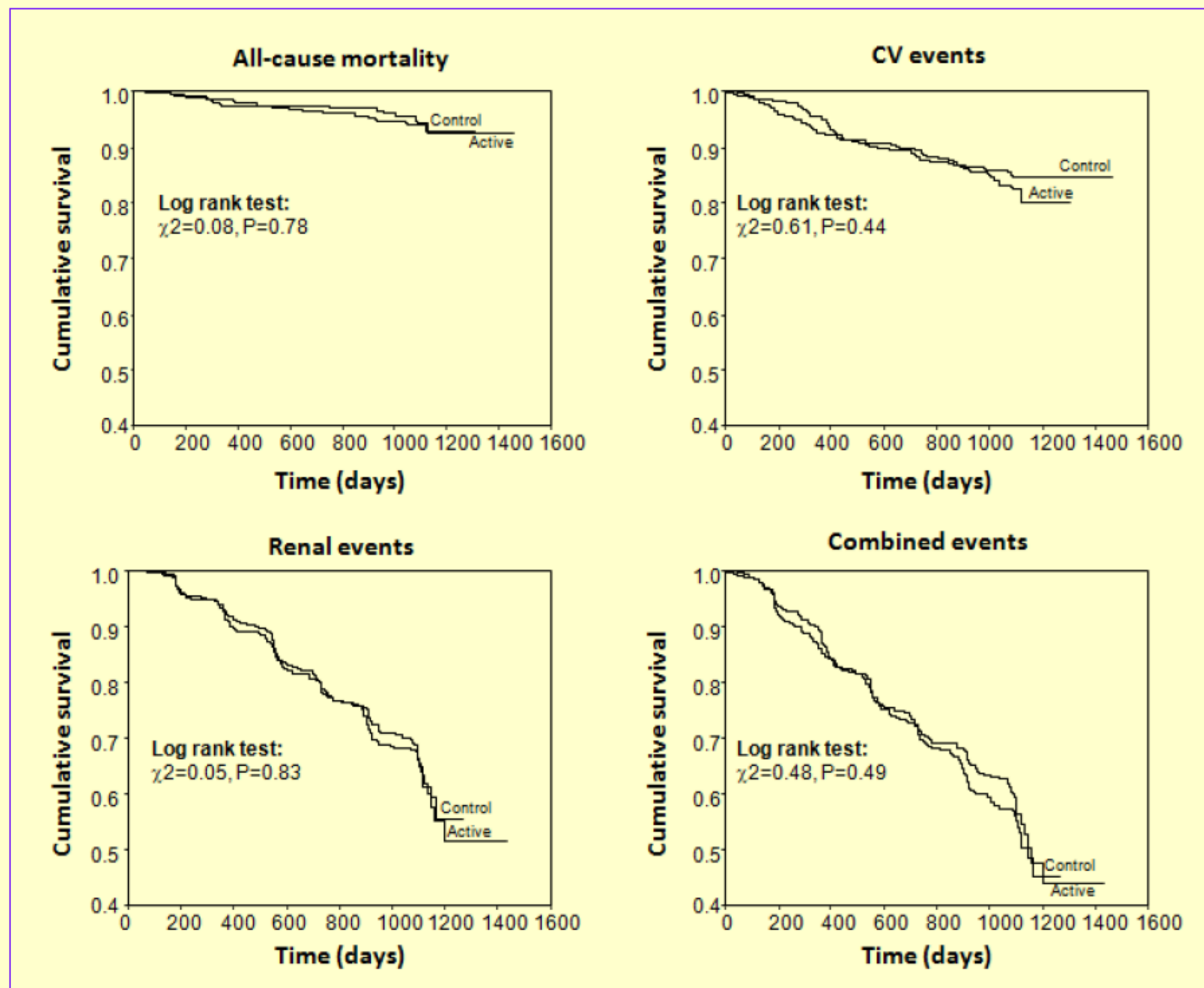
	% change (follow up – baseline)		active vs control group
	active arm	control arm	P (MLM)
Systolic BP	-8%	-6%	0.59
Diastolic BP	-9%	-7%	0.29
Proteinuria	-25%	-39%	0.66
Cholesterol	-13%	-10%	0.32
Serum calcium	-0.5%	-0.8%	0.11
Serum phosphate	-6%	-22%	0.21
Hemoglobin	+15%	+11%	0.52
Parathormone	+29%	+25%	0.62

Table

Conclusions:

A multimethod quality intervention aimed at enhancing nephrologists knowledge and applying reminders about patients out of clinical targets and clinical audits failed to show better outcomes as compared to a less intensive intervention (education on Guidelines at baseline). Results in this trial matched those of previous pharmacological clinical trials in the Italian population. In both study arms important risk factors for CKD progression, like hypertension control and proteinuria, improved over time indicating a beneficial effect of background education on Guidelines but little benefit of knowledge refreshing and clinical audits.

References:

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MAURO Working group:

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