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Session Assignment: LBS.04 – Using Drugs, Diet and Delivery to Optimize Hypertension Outcomes

Effectiveness of Blood Pressure-Lowering Intervention on Risk of Total Dementia Among Patients With Hypertension: A Cluster-Randomized Effectiveness Trial

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Abstract Content:
Background: Dementia is a leading cause of deaths and disability worldwide. Currently, there are no proven interventions that prevent or delay the development of dementia. We tested the effectiveness of intensive blood pressure (BP) lowering intervention on dementia risk among hypertensive patients in rural China.
Methods: In this cluster-randomized effectiveness trial, we recruited individuals aged ≥40 years with an untreated BP ≥140/90 mmHg (≥130/80 mmHg for those at high risk for cardiovascular disease or if currently taking antihypertensive medication). We randomly assigned 163 villages to a non-physician community health-care provider-led intervention and 163 villages to usual care. In the intervention group, trained nonphysician community health-care providers initiated and titrated antihypertensive medications according to a simple stepped-care protocol to achieve a systolic BP goal of <130 mmHg and diastolic BP goal of <80 mm Hg with supervision from primary care physicians. The primary cognitive outcome was adjudicated dementia. Secondary cognitive outcomes included adjudicated cognitive impairment, a composite outcome of dementia or cognitive impairment, and all-cause mortality. All clinical events were adjudicated independently by two neurologists blinded to intervention assignments according to a standard protocol. Intention to treat analysis was conducted.
Results: At 48 months, the mean systolic and diastolic blood pressures (BP) were 127.6 and 72.6 mmHg in the intervention group, respectively, and 147.7 and 81.0 mmHg in the usual care group. The net change in systolic BP was -22.0 (95% CI -23.4 to -20.6, p<0.0001), and the net change in diastolic BP was -9.3 (-10.0 to -8.7, p<0.0001). The primary outcome of dementia was significantly lower in the intervention group compared to the usual care group (1.12% vs. 1.31% per year; relative risk with intervention: 0.85, 95% CI: 0.76 to 0.95; p=0.0035). Cognitive impairment alone, the composite outcome of dementia or cognitive impairment, death from all causes, and the composite outcome of dementia or deaths were all significantly lower in the intervention group compared to the usual care group (see **Table**). Serious adverse events (deaths or hospitalizations) were also less frequent in the intervention group.

Conclusion: This is the first ever large cluster-randomized effectiveness trial to demonstrate that BP lowering is effective in reducing risk of dementia in patients with hypertension. This proven-effective intervention should be widely scaled up to reduce the global burden of dementia. (ClinicalTrials.gov: NCT03527719)

Table. Effectiveness of blood pressure-lowering intervention on the primary and secondary outcomes

Study outcomes	Intervention		Usual care		Unadjusted relative risk (95% CI)*	P value	Multiple-adjusted relative risk (95% CI)†	P value
	No. of events	Rate, % per year	No. of events	Rate, % per year				
Primary outcome								
Total dementia	668	1.12	734	1.31	0.85 (0.76, 0.95)	0.0035	0.88 (0.79, 0.98)	0.0229
Secondary outcomes								
Cognitive impairment	2506	4.19	2808	5.02	0.84 (0.80, 0.87)	<0.0001	0.85 (0.81, 0.89)	<0.0001
Composite outcome of dementia or cognitive impairment	3174	5.31	3542	6.34	0.84 (0.81, 0.87)	<0.0001	0.86 (0.83, 0.90)	<0.0001
Death from all causes	1269	1.87	1392	2.17	0.87 (0.80, 0.94)	0.0004	0.88 (0.82, 0.94)	0.0003
Composite outcome of dementia or deaths	1908	3.04	2092	3.54	0.86 (0.81, 0.92)	<0.0001	0.88 (0.83, 0.94)	<0.0001
Serious adverse event‡	6201	9.16	6329	9.86	0.94 (0.91, 0.98)	0.0006	0.94 (0.91, 0.97)	<0.0001

* Stratified by village, town, county, and province.

† Stratified by village, town, county, and province and adjusted for age, sex, cigarette smoking, history of major cardiovascular disease, use of antihypertensive medication, systolic blood pressure, low-density lipoprotein cholesterol, and fasting plasma glucose at baseline.

‡ Serious adverse events included deaths and hospitalizations in this analysis.