HEALTHY HEART

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Honorary Editor:
Dr. Anish Chandarana
Interventional Cardiologist

From the Desk of Hon. Editor:

Hello Friends

Greeting

Aspirin has existed for many more years than each of the doctor using it.

Still there is a lot of confusion regarding its use for primary prevention of cardio-vascular disease. This review will help to provide us clarity as the said subject.

Best wishes

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ASPIRIN For Primary Prevention: YES, or NO?

The role of aspirin for secondary prevention of myocardial infarction (MI), stroke, or transient ischemic attack (TIA) is well established. However, the efficacy and safety of aspirin for primary prevention of cardiovascular disease (CVD) varied among multiple randomized controlled trials (RCTs), creating significant variability in guidelines. Long-term aspirin use has also been historically associated with a reduction in colorectal cancer (CRC) incidence and mortality. The recently published 10-year follow-up of the JPAD 2 study (Japanese Primary Prevention of Atherosclerosis with Aspirin for Diabetes), as well as 3 large RCTs, ARRIVE (Aspirin to Reduce Risk of Initial Vascular Events), ASCEND (A Study of Cardio-vascular Events in Diabetes), and ASPREE (Aspirin in Reducing Events in the Elderly), added more data to the existing debate.

Two systematic reviews published recently in JAMA (Association of Aspirin Use for Primary Prevention With Cardiovascular Events and Bleeding Events A Systematic Review and Meta-analysis – 13 RCTs, 164 225 participants; Sean L. Zheng, BM, BCh, MA, MRCP; Alistair J. Roddick, BSc: January 22, 2019 Volume 321, Number 3) and in JACC (Aspirin for Primary Prevention of Cardiovascular Events – 15 RCTs, 165,502 participants; Hesham K. Abdelaziz, MD, PHD,a,b,* Marwan Saad, MD, PHD,b,c,* Naga Venkata K. Pothineni, MD,c Michael Megaly, MD, MS,d,e Rahul Potluri, MD,f Mohammed Saleh, MD,g David Lai Chin Kon, MD,a David H. Roberts, MD,a Deepak L. Bhatt, MD, MPH,h Herbert D. Aronow, MD, MPH,i J. Dawn Abbott, MD,i Jawahar L. Mehta, MD, PHD: JACC VOL. 73, NO. 23, 2019 JUNE 18, 2019:2915 – 29) represent the most comprehensive analysis of the available data to evaluate the efficacy and safety of aspirin for primary prevention of CVD as well as its effect on cancer incidence and mortality within the period of follow-up.

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First 5 tables are taken from the above-mentioned JAMA article and the last figure is taken from JACC article.

Key Highlights:

1. This body of evidence shows that aspirin use for primary prevention of CVD is associated with a decreased risk for myocardial infarction and stroke, but not cardiovascular mortality or all-cause mortality. Results are quite similar when studies using all doses of aspirin are compared with studies using low-dose aspirin (⩽100 mg/day).

2. When looking at studies reporting on the harms of low-dose aspirin use (⩽100 mg/day), which is most relevant to current practice, a pooled analysis of 10 trials showed that aspirin use was associated with a 58% increase in major gastrointestinal bleeding and a pooled analysis of 11 trials showed a 31% increase in intracranial bleeds in the aspirin group compared with the control (placebo or no aspirin) group. ***(Figure 1)*** Low-dose aspirin use was not associated with a statistically significant increase in risk for fatal haemorrhagic stroke.

3. Data suggested that the increased risk for bleeding associated with aspirin use occurs relatively quickly after initiating aspirin, and data do not suggest that aspirin has a differential relative bleeding risk based on age, sex, presence of diabetes, level of CVD risk, or race or ethnicity. Although the increase in relative risk does not appear to differ based on age, the absolute risk for bleeding and thus, the magnitude of bleeding harm does increase with age, and more so in adults with age 60 years and older.

4. Aspirin use has a small net benefit in persons ages 40 to 59 years with 10% or greater 10-year CVD risk, and initiation of aspirin use has no net benefit in persons aged 60 years or older. Modelling data demonstrated that aspirin use in both men and women ageing 40 to 59 years with 10% or greater 10-year CVD risk generally provides a modest net benefit in both quality-adjusted life-years and life-years gained. Initiation of aspirin use in persons ages 60 to 69 years results in quality-adjusted life-years gained that range from slightly negative to slightly positive, depending on CVD risk level, and life-years gained are generally negative.

5. In persons aged 70 to 79 years, initiation of aspirin use results in a loss of both quality-adjusted life-years and life-years at essentially all CVD risk levels modeled (ie, up to 20% 10-year CVD risk). - ***(Figure 2 (A & B))***

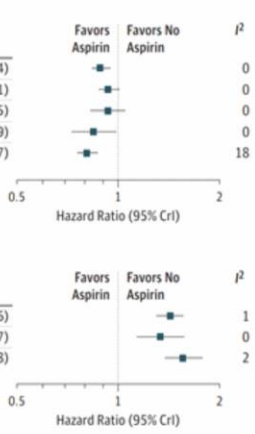
6. When looking at net lifetime benefit of continuous aspirin use until stopping at age 65, 70, 75, 80, or 85 years, modelling data suggest that there is generally little incremental lifetime net benefit in continuing aspirin use beyond the ages of 75 to 80 years.

7. The net benefit of continuing aspirin use by a person in their 60s or 70s is not the same as the net benefit of initiating aspirin use by a person in their 60s or 70s. This is because, in part, of the fact that CVD risk is heavily influenced by age. ***(Figure 2 (C)*** Persons who meet the eligibility criteria for aspirin use at a younger age (i.e., ⩾ 10% 10-year CVD risk in their 40s or 50s) typically have even higher CVD risk by their 60s or 70s compared with persons who first reach a 10% or greater 10-year CVD risk in their 60s or 70s, and may gain more benefit by continuing aspirin use than a person at lower risk might gain by initiating aspirin use.

Figure 1 : Cardiovascular and Bleeding Outcomes in All Participants

Cardiovascular Outcomes	No. of Studies	Aspirin No. of Events	Aspirin No. of Participants	No Aspirin No. of Events	No Aspirin No. of Participants	Absolute Risk Reduction, % (95% CI)	HR (95% CrI)	I^2
Composite CV outcome	13	2911	79717	3342	80057	0.41 (0.23 to 0.59)	0.89 (0.84-0.94)	0
All-cause mortality	13	3622	81623	3588	80057	0.13 (-0.07 to 0.32)	0.94 (0.88-1.01)	0
CV mortality	13	995	81623	997	80057	0.07 (-0.04 to 0.17)	0.94 (0.83-1.05)	0
Myocardial infarction	13	1469	81623	1599	80057	0.28 (0.05 to 0.47)	0.85 (0.73-0.99)	0
Ischemic stroke	10	831	65316	942	63752	0.19 (0.06 to 0.30)	0.81 (0.76-0.87)	18

Bleeding Outcomes	No. of Studies	Aspirin No. of Events	Aspirin No. of Participants	No Aspirin No. of Events	No Aspirin No. of Participants	Absolute Risk Increase, % (95% CI)	HR (95% CrI)	I^2
Major bleeding	11	1195	74715	834	73143	0.47 (0.34 to 0.62)	1.43 (1.30-1.56)	1
Intracranial bleeding	12	349	80985	257	79419	0.11 (0.04 to 0.18)	1.34 (1.14-1.57)	0
Major GI bleeding	10	593	70336	380	70465	0.30 (0.20 to 0.41)	1.56 (1.38-1.78)	2

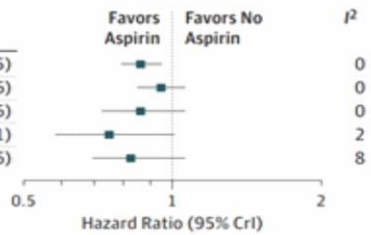


The composite cardiovascular (CV) outcome consisted of cardiovascular mortality, nonfatal myocardial infarction, and nonfatal stroke. Hazard ratios (HRs) and 95% credible interval variables (CrIs) were calculated using Bayesian meta-analysis of trial-level event counts. The absolute risk reductions and increases were calculated by multiplying the control event risk by the relative risk and 95% CIs derived by frequentist meta-analysis (eFigure 4 in Supplement 2). GI indicates gastrointestinal.

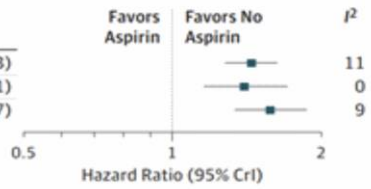
Figure 2 : Cardiovascular and Bleeding Outcomes for Studies with Patients at High and Low Risk for the Primary CV Outcome and with Diabetes

A Participants with low CV risk

Cardiovascular Outcomes	No. of Studies	Aspirin: No. of Events	Aspirin: No. of Participants	No Aspirin: No. of Events	No Aspirin: No. of Participants	Absolute Risk Reduction, % (95% CI)	HR (95% CrI)	I^2
Composite CV outcome	6	1559	56212	1753	56354	0.34 (0.14 to 0.52)	0.87 (0.79-0.95)	0
All-cause mortality	6	1903	56212	1905	56354	0.01 (-0.27 to 0.27)	0.95 (0.85-1.06)	0
CV mortality	6	405	56212	448	56354	0.07 (-0.03 to 0.16)	0.87 (0.72-1.06)	0
Myocardial infarction	6	649	56212	793	56354	0.27 (0.00 to 0.49)	0.75 (0.58-1.01)	2
Ischemic stroke	5	508	49942	593	50078	0.16 (0.02 to 0.29)	0.83 (0.69-1.06)	8

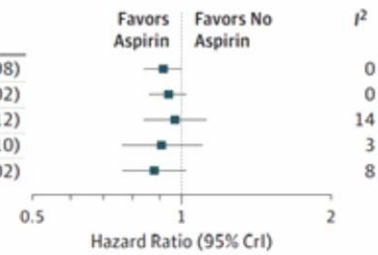


Bleeding Outcomes	No. of Studies	Aspirin: No. of Events	Aspirin: No. of Participants	No Aspirin: No. of Events	No Aspirin: No. of Participants	Absolute Risk Increase, % (95% CI)	HR (95% CrI)	I^2
Major bleeding	5	665	49942	465	50078	0.40 (0.25 to 0.57)	1.45 (1.28-1.63)	11
Intracranial bleeding	6	245	56212	175	56354	0.13 (0.05 to 0.22)	1.41 (1.16-1.71)	0
Major GI bleeding	5	359	48992	228	49110	0.27 (0.15 to 0.40)	1.58 (1.34-1.87)	9

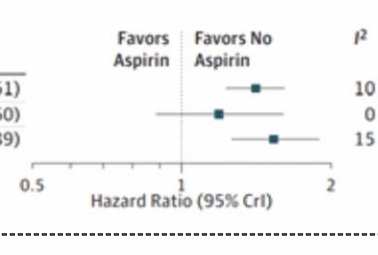


B Participants with high CV risk

Cardiovascular Outcomes	No. of Studies	Aspirin: No. of Events	Aspirin: No. of Participants	No Aspirin: No. of Events	No Aspirin: No. of Participants	Absolute Risk Reduction, % (95% CI)	HR (95% CrI)	I^2
Composite CV outcome[a]	8	1645	25411	1649	23703	0.63 (0.18 to 1.04)	0.91 (0.84-0.98)	0
All-cause mortality	7	1719	25411	1683	23703	0.43 (-0.02 to 0.84)	0.94 (0.86-1.02)	0
CV mortality	7	590	25411	549	23703	0.04 (-0.27 to 0.32)	0.97 (0.84-1.12)	14
Myocardial infarction[a]	8	820	25411	806	23703	0.32 (-0.16 to 0.74)	0.91 (0.76-1.10)	3
Ischemic stroke[a]	6	323	15374	350	13674	0.28 (-0.12 to 0.63)	0.88 (0.76-1.02)	8

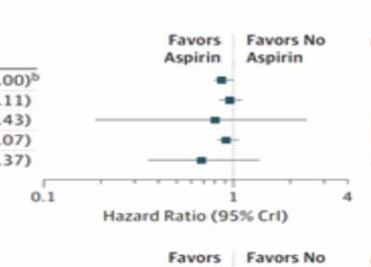


Bleeding Outcomes	No. of Studies	Aspirin: No. of Events	Aspirin: No. of Participants	No Aspirin: No. of Events	No Aspirin: No. of Participants	Absolute Risk Increase, % (95% CI)	HR (95% CrI)	I^2
Major bleeding	6	530	24773	369	23065	0.64 (0.35 to 0.97)	1.41 (1.23-1.61)	10
Intracranial bleeding	6	104	24773	82	23065	0.07 (-0.04 to 0.21)	1.19 (0.89-1.60)	0
Major GI bleeding	5	34	19452	30	19444	0.39 (0.16 to 0.69)	1.54 (1.26-1.89)	15

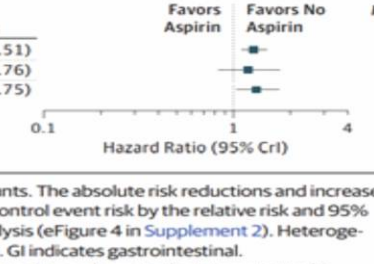


C Participants with diabetes

Cardiovascular Outcomes	No. of Studies	Aspirin: No. of Events	Aspirin: No. of Participants	No Aspirin: No. of Events	No Aspirin: No. of Participants	Absolute Risk Reduction, % (95% CI)	HR (95% CrI)	I^2
Composite CV outcome	8	977	14916	1072	14898	0.65 (0.09 to 1.17)	0.90 (0.82-1.00)[b]	0
All-cause mortality	5	1028	11938	1055	11946	0.24 (-0.49 to 0.91)	0.97 (0.85-1.11)	0
CV mortality	4	264	10159	279	10167	0.05 (-1.27 to 0.94)	0.82 (0.19-2.43)	35
Myocardial infarction	8	472	11788	490	11700	0.26 (-0.47 to 0.88)	0.94 (0.83-1.07)	14
Ischemic stroke	3	275	9535	317	9511	0.83 (-0.50 to 1.70)	0.70 (0.36-1.37)	23



Bleeding Outcomes	No. of Studies	Aspirin: No. of Events	Aspirin: No. of Participants	No Aspirin: No. of Events	No Aspirin: No. of Participants	Absolute Risk Increase, % (95% CI)	HR (95% CrI)	I^2
Major bleeding	3	370	10029	287	10047	0.80 (0.29 to 1.39)	1.29 (1.11-1.51)	0
Intracranial bleeding	2	63	9002	52	9017	0.12 (-0.09 to 0.43)	1.21 (0.84-1.76)	1
Major GI bleeding	2	142	9002	105	9017	0.41 (0.06 to 0.86)	1.35 (1.05-1.75)	1

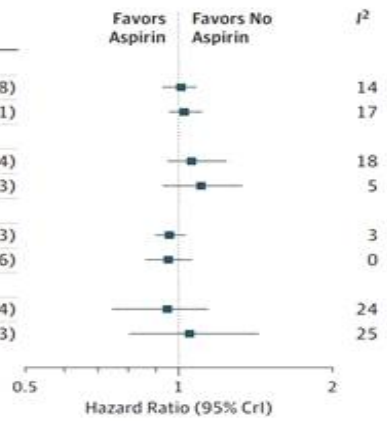


Cardiovascular and bleeding outcomes for studies in which the risk of the primary cardiovascular outcome were low and high, and in participants with diabetes. Trials were low or high risk if the 10-year cardiovascular (CV) risk for the primary CV outcome was less than 10% or greater than or equal to 10%, respectively. The composite CV outcome included CV mortality, nonfatal myocardial infarction, and nonfatal stroke. Hazard ratios (HRs) and 95% credible intervals (CrIs) were calculated using Bayesian meta-analysis of event counts. The absolute risk reductions and increases were calculated by multiplying the control event risk by the relative risk and 95% CIs derived by frequentist meta-analysis (eFigure 4 in Supplement 2). Heterogeneity was assessed using I^2 statistics. GI indicates gastrointestinal.

[a]The number of participants randomized to each arm in the Women's Health Study[24] was not reported, so event counts are omitted. [b]Upper CrI: 0.997.

Figure 3 : Exploratory Cancer Outcomes

Efficacy	No. of Studies	Aspirin No. of Events	Aspirin No. of Participants	No Aspirin No. of Events	No Aspirin No. of Participants	Absolute Risk Difference, % (95% CI)	HR (95% CrI)	I^2
All participants								
Incident cancer	10	4507	63048	4409	61475	0.03 (-0.37 to 0.46)	1.01 (0.93-1.08)	14
Cancer mortality	12	1530	75353	1447	73781	0.05 (-0.11 to 0.23)	1.03 (0.96-1.11)	17
Low CV risk participants								
Incident cancer	4	2837	38905	2730	39044	0.41 (-0.13 to 1.01)	1.06 (0.95-1.24)	18
Cancer mortality	5	823	49942	748	50078	0.16 (-0.06 to 0.42)	1.11 (0.93-1.33)	5
High CV risk participants								
Incident cancer	6	1670	24143	1679	22431	-0.30 (-0.76 to 0.19)	0.96 (0.90-1.03)	3
Cancer mortality	7	707	25411	699	23703	-0.13 (-0.41 to 0.17)	0.96 (0.86-1.06)	0
Participants with diabetes								
Incident cancer	3	1091	9640	1116	9655	-0.68 (-2.09 to 0.95)	0.95 (0.74-1.14)	24
Cancer mortality	4	445	10667	438	10685	0.16 (-0.56 to 1.02)	1.05 (0.80-1.43)	25



Cancer outcomes across all studies, in low and high cardiovascular risk populations, and in patients with diabetes. The absolute risk reductions and increases were calculated by multiplying the control event risk by the relative risk, and 95% CIs derived by frequentist meta-analysis (eFigure 4 in Supplement 2). Study heterogeneity was assessed using I^2 statistics. HR indicates hazard ratio; CrI indicates credible interval; CV indicates cardiovascular. Data for the JPAD, JPPP, and WHS trials were extracted from subsequent trial publications on cancer outcomes.[29-31] Data for the HOT, BDS, and PHS (cancer mortality) and the HOT, BDS, AAA, and POPADAD (incident cancer) trials were extracted from previous meta-analyses on cancer outcomes.[14]

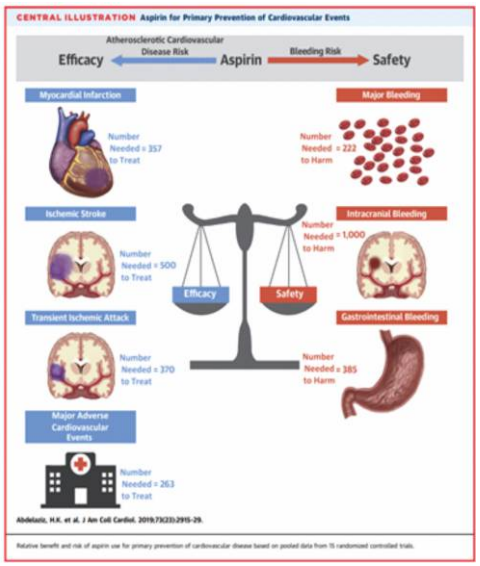
Conclusions:

1. The decision to initiate low-dose aspirin use for the primary prevention of CVD in adults aged 40 to 59 years who have a 10% or greater 10-year cardiovascular risk should be individualized. Evidence indicates that the net benefit of aspirin use in this group is small. Persons who are not at increased risk for bleeding (baseline characteristics such as older age, male sex, history of GI ulcers, elevated mean BP, and NSAID use, have shown to increase the risk of aspirin-related bleeding) and are willing to receive low-dose aspirin daily are more likely to benefit. The benefits of initiating aspirin use are greater for individuals at higher risk for CVD events (e.g., those with >15% -20% 10-year CVD risk).

2. It is not recommended to initiate low-dose aspirin for the primary prevention of CVD in adults aged 60 years or older. It has no net benefit or the harms might outweigh the benefits.

3. Decisions about initiating aspirin use should be based on shared decision making between clinicians and patients about the potential benefits and harms. Persons who place a higher value on the potential benefits than the potential harms may choose to initiate low-dose aspirin use. Persons who place a higher value on the potential harms or on the burden of taking a daily preventive medication than the potential benefits may choose not to initiate low-dose aspirin use.

4. Risk for bleeding increases modestly with advancing age. For persons who have initiated aspirin use, the net benefits continue to accrue over time in the absence of a bleeding event. The net benefits become smaller with advancing age because of an increased risk for bleeding. Modelling data suggest that it may be reasonable to consider stopping aspirin use around age of 75 years.



5.Based on new analyses of the evidence from primary CVD prevention populations, longer-term follow up data from the Women's Health Study (WHS) and new trial evidence, the evidence is inadequate that low-dose aspirin use reduces colorectal cancer incidence or mortality.

6.The benefit appears similar for a low dose (⩽ 100 mg/day) and all doses that have been studied in CVD prevention trials (50 to 500 mg/day). A pragmatic approach would be to use 75/81/100 mg of aspirin daily, which is the most commonly available and prescribed dose.

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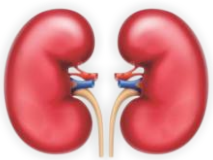
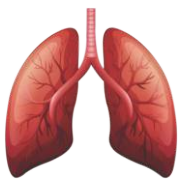
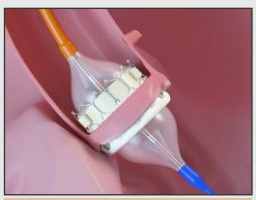


Kidney Transplant

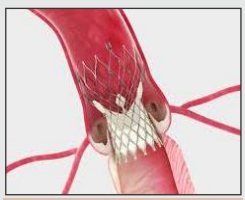
Paediatric BMT



Lung Transplant



Balloon Expandable Valve



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