| Study | Outcome (unit) | Followup (years) | N Analyzed | Group | Results | Between Group Difference |
| --- | --- | --- | --- | --- | --- | --- |
| AMIS, 198075  Fair | Duodenal ulcer, hospitalization (number of participants) | 3.2 | 2267 | ASA | 21 (0.9%) | ASA vs. Placebo: RR 10.5 (95% CI, 2.9 to 66.4), p=NR |
| 2257 | Placebo | 2 (0.09%) |
| Gastric ulcer, hospitalization (number of participants) | 3.2 | 2267 | ASA | 12 (0.5%) | ASA vs. Placebo: RR 6.0 (95% CI, 1.5 to 39.6), p=NR |
| 2257 | Placebo | 2 (0.09%) |
| Peptic ulcer (number of participants) | 3.2 | 2267 | ASA | NR (NR) | ASA vs. Placebo: RR 7.7 (95% CI, 2.7 to 21.7), p≤0.0001\* |
| 2257 | Placebo | NR (NR) |
| Peptic ulcer, gastritis, erosion of gastric mucosa symptoms (number of participants) | 3.2 | 2267 | ASA | 537 (23.7%) | ASA vs. Placebo: Z-score 7.52, p=NR |
| 2257 | Placebo | 336 (14.9%) |
| Ulcer diagnosis during hospitalization for GI problems (number of participants) | 3.2 | 2267 | ASA | 29 (1.3%) | NR |
| 2257 | Placebo | 5 (0.2%) |
| CDPRG, 1980 (CDPA)59  Good | Ulcer, peptic (number of participants) | 1.8 | 727 | ASA | 20 (2.8%) | ASA vs. Placebo: Z-value 0.75, p=NR |
| 744 | Placebo | 16 (2.2%) |
| Cook, 2005 (WHS)60  Good (KQ1,KQ2); Fair (KQ6) | Ulcer, peptic (number of events) | 10.1 | 19934 | ASA | 542 (2.7) | ASA vs. No ASA: RR 1.32 (95% CI, 1.16 to 1.50), p≤0.001† |
| 19942 | No ASA | 413 (2.1) |
| Ulcer, peptic (per 1,000 person-years) | 10.1 | 19934 | ASA | 2.76 (NR) | ASA vs. No ASA: Rate Difference 0.66 (95% CI, 0.35 to 0.97), p=NR |
| 19942 | No ASA | 2.10 (NR) |
| *Cook, 2013 (Companion publication to Cook, 2005) 980 88*  *Good* | *Ulcer, peptic (number of cases)* | *10* | *19934* | *ASA* | *1115 (5.6)* | *ASA vs. No ASA: HR 1.20 (95% CI, 1.10 to 1.31), p≤0.001†* |
| *19942* | *No ASA* | *931 (4.7)* |
| *Ulcer, peptic (number of cases)* | *11-18 (post-trial)* | *19934* | *ASA* | *341 (2.0)* | *ASA vs. No ASA: HR 1.09 (95% CI, 0.94 to 1.28), p=0.26†* |
| *19942* | *No ASA* | *311 (1.8)* |
| *Ulcer, peptic (number of cases)* | *18* | *19934* | *ASA* | *1456 (7.3)* | *ASA vs. No ASA: HR 1.17 (95% CI, 1.09 to 1.27), p≤0.001†* |
| *19942* | *No ASA* | *1242 (6.2)* |
| DAMAD, 198951  Fair | Ulcer, cause for discontinuation (number of participants) | 3 | 157 | ASA | 5 (3.2%) | NR |
| 157 | Placebo | 1 (0.6%) |
| Diener, 1997 (ESPS-2)62  Good | Duodenal ulcer bleeding, hospitalization and transfusion (number of participants) | 2 | 1649 | ASA | 1 (0.06%) | NR |
| 1649 | Placebo | 0 (0%) |
| Ulcer, gastro-duodenal (number of events) | 2 | 1649 | ASA | 1 (NR) | NR |
| 1649 | Placebo | 2 (NR) |
| Ekstrom, 2013 (SNDR)86  Fair | Ulcer, ventricular (number of events) | 4 | 18646 | All Participants | 93 (0.5) | ASA vs. No ASA: HR 1.64 (95% CI, 1.06 to 2.53), p=0.02‡ |
| 18646 | All Participants | 1.4 (NR) |
| Fowkes, 2010 (AAA)66  Good | Ulcer, GI (number of events) | 8.2 | 65 | ASA | 15 (NR) | NR |
| 59 | Placebo | 11 (NR) |
| Ulcer, GI (number of participants) | 8.2 | 1675 | ASA | 14 (0.8%) | NR |
| 1675 | Placebo | 8 (0.5%) |
| Logan, 2008 (ukCAP)68  Fair | Ulcer, peptic (number of participants) | 3.4 | 472 | ASA | 3 (0.6%) | NR |
| 467 | No ASA | 1 (0.2%) |
| PARIS, 1980 71  Good | Symptoms suggestive of peptic ulcer, gastritis, or gastric mucosa erosion (as reported by physician) (number of participants) | 3.4 | 810 | ASA | 147 (18.1%) | ASA vs. Placebo: Z-value 2.09, p=NR |
| 406 | Placebo | 54 (13.2%) |
| Peto, 1988 (BMD)72  Fair | Ulcer, peptic (per 10,000 person-years) | 6 | 3429 | ASA | 46.8 (NR) | ASA vs. No ASA: p≤0.05 |
| 1710 | No ASA | 29.6 (NR) |
| PHS, 1989 843 73  Good (KQ1); Fair (KQ6) | Ulcer, duodenal (number of participants) | 5 | 11037 | ASA | 46 (0.4%) | ASA vs. Placebo: p=0.03§ |
| 11034 | Placebo | 27 (0.2%) |
| Ulcer, esophageal (number of participants) | 5 | 11037 | ASA | 11 (0.1%) | ASA vs. Placebo: p=0.23§ |
| 11034 | Placebo | 6 (0.05%) |
| Ulcer, gastric (number of participants) | 5 | 11037 | ASA | 25 (0.2%) | ASA vs. Placebo: p=0.11§ |
| 11034 | Placebo | 15 (0.1%) |
| Ulcer, gastrojejunal (number of participants) | 5 | 11037 | ASA | 3 (0.03%) | ASA vs. Placebo: p=0.70§ |
| 11034 | Placebo | 4 (0.04%) |
| Ulcer, peptic (number of participants) | 5 | 11037 | ASA | 156 (1.4%) | ASA vs. Placebo: p=0.11§ |
| 11034 | Placebo | 129 (1.2%) |
| Ulcer, some hemorrhage (number of participants) | 5 | 11037 | ASA | 38 (0.3%) | ASA vs. Placebo: RR 1.77 (95% CI, 1.07 to 2.94), p=0.04§ |
| 11034 | Placebo | 22 (0.2%) |
| Ulcer, upper GI (number of participants) | 5 | 11037 | ASA | 169 (1.5%) | ASA vs. Placebo: RR 1.22 (95% CI, 0.98 to 1.53), p=0.08§ |
| 11034 | Placebo | 138 (1.3%) |

\*Multivariate adjusted

†Adjusted by age, vitamin E and beta-carotene treatment assignment

‡Stratification w/ propensity score decile, age, sex, DM duration, hospitalization, hypoglycemic treatment, HbA1c, smoking, BMI, SBP, ratio TC:HDL, albuminuria > 20ug/min, anti-HTN, statins, other lipid-lowering drugs, estrogen, multidose

§Adjusted by age and beta-carotene assignment

**Abbreviations**: ASA = acetylsalicylic acid; CI = confidence interval; GI = gastrointestinal; HR = hazard ratio; NR = not reported; RR = relative risk