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Risk of Upper Gastrointestinal Bleeding Associated With Use of Low-Dose Aspirin

Henrik Toft Sørensen, M.D., Ph.D., Lene Mellemkjær, Ph.D., William J. Blot, Ph.D., Gunnar Lauge Nielsen, M.D., Flemming Hald Steffensen, M.D., Joseph K. McLaughlin, Ph.D., and Jørgen H. Olsen, M.D., Ph.D.

Department of Clinical Epidemiology, Aarhus University and Aalborg Hospitals, Aarhus, Denmark; The Institute of Cancer Epidemiology, The Danish Cancer Society, Copenhagen, Denmark; The International Epidemiology Institute, Rockville, Maryland; The Department of Medicine M, Aalborg Hospital, Aalborg, Denmark; and the Danish Epidemiology Science Centre at the Department of Epidemiology and Social Medicine, University of Aarhus, Aarhus, Denmark

OBJECTIVE: Aspirin products are known to cause irritation and injury to the gastric mucosa. We examined the risk of hospitalization for upper gastrointestinal bleeding with use of low-dose aspirin.

METHODS: This was a cohort study based on record linkage between a population-based prescription database and a hospital discharge registry in North Jutland County, Denmark, from January 1, 1991, to December 31, 1995. Incidence rates of upper gastrointestinal bleeding in 27,694 users of low-dose aspirin were compared with the incidence rates in the general population in the county.

RESULTS: A total of 207 exclusive users of low-dose aspirin experienced a first episode of upper gastrointestinal bleeding with admission to the hospital during the study period. The standardized incidence rate ratio was 2.6 (95% confidence interval, 2.2–2.9), 2.3 in women and 2.8 in men. The standardized incidence rate ratio for combined use of low-dose aspirin and other nonsteroidal anti-inflammatory drugs was 5.6 (95% confidence interval, 4.4–7.0). The risk was similar among users of noncoated low-dose aspirin (standardized incidence rate ratio, 2.6; 95% confidence interval, 1.8–3.5) and coated low-dose aspirin (standardized incidence rate ratio, 2.6; 95% confidence interval, 2.2–3.0).

CONCLUSIONS: Use of low-dose aspirin was associated with an increased risk of upper gastrointestinal bleeding, with still higher risks when combined with other nonsteroidal anti-inflammatory drugs. Enteric coating did not seem to reduce the risk. The findings from this observational study raise the possibility that prophylactic use of low-dose aspirin may convey an increased risk of gastrointestinal bleeding, which may offset some of its benefits. (Am J Gastroenterol 2000;95:2218–2224. © 2000 by Am. Coll. of Gastroenterology)

INTRODUCTION

Aspirin is one of the oldest and most widely used drugs in the world. Standard doses of 750–1000 mg are used for pain relief, whereas the use of low-dose aspirin is increasing in secondary prevention of cardiovascular disease (1). The most frequent side effects of aspirin are related to the gastrointestinal (GI) tract (2, 3). Many animal and human studies have shown that aspirin causes gastric mucosal erosions and inhibition of thromboxane synthesis (4). Standard doses of aspirin are associated with a substantial risk of upper GI bleeding, but our knowledge about the risk associated with low doses is mainly limited to a few randomized trials and case-control studies, some of which suggest that no aspirin regimen is free of the risk of upper GI bleeding (5–16). Upper GI bleeding is a common reason for admission to the hospital, especially among the elderly, and has an estimated case fatality rate of 8% (17, 18). Moreover, aspirin has often not been included in studies of the risk of upper GI bleeding associated with use of nonsteroidal anti-inflammatory drugs (NSAIDs), because of underascertainment of exposure (19, 20).

Because aspirin is used so widely, even small risks of side effects have major clinical and public health implications. On this background, we conducted a population-based cohort study in Denmark to examine: 1) the risk of upper GI bleeding associated with use of low-dose aspirin, adjusted for use of other drugs that may increase the risk of bleeding; 2) whether concurrent nonaspirin NSAID treatment affects the risk of bleeding; and 3) whether enteric coating reduces the risk of bleeding.

MATERIALS AND METHODS

The study was carried out within the population of the county of North Jutland in Denmark, which comprised about 490,000 inhabitants, approximately 9% of the total Danish population, during the study period 1991 to 1995.

The National Health Service provides tax-supported health care for all inhabitants, guaranteeing free access to general practitioners, hospitals, and public clinics and refunding a variable proportion of the costs of drugs prescribed by physicians. The population-based Pharmaco-Epidemiological Prescription Database of North Jutland (21, 22), initiated on January 1, 1991, retains key information on prescriptions for refundable drugs dispensed from all 33 pharmacies in the county. This includes the personal identification number of the customer, type of drug prescribed according to the anatomical therapeutical chemical (ATC) classification system (23), and the date of prescription (date of dispensing the drug). The personal identification number comprises 10 digits that encode gender and date of birth. With its use, a complete prescription history can be established for each individual, and unambiguous linkages with other registers can be performed.

In the Pharmaco-Epidemiological Prescription Database we identified 30,952 users of low-dose tablets of 100 mg (19.2%) or 150 mg (80.8%) of aspirin during the period 1991–1995. Regular use of low-dose aspirin for prevention of cardiovascular disease is most likely prescribed by doctors in Denmark, for which the patients get 50% of the cost refunded. Record linkage with the Danish mortality files resulted in the exclusion of 29 persons (0.1%) because of a date of death before the date of aspirin prescription, or to an error in the identification number. We also excluded 15 users (<0.1%) who were aged <16 yr or >105 yr at the date of the aspirin prescription, and 602 users (2.0%) who were not residents in the county. The remaining 30,306 persons were linked to the Regional Hospital Discharge Register (HDR), which, on a permanent basis, retains key information on all patients discharged from somatic hospitals in the county during 1977–1995 (24). The files of the HDR include information on the identification number of the patient, date of discharge, and up to 20 discharge diagnoses (24), coded according to the Danish version of the International Classification of Diseases, the 8th revision (24) until the end of 1993, and the 10th revision (24) since. Based on the hospital discharge history, we decided to exclude an additional 961 persons because, before the date of the first notified aspirin prescription, they had been diagnosed with an upper GI bleeding (n = 437; 1%), which was the outcome of the present investigation, *i.e.*, bleeding caused by a gastric, duodenal, or gastrojejunal ulcer as well as hematemesis and melena (22) (ICD-8 = 530.98, 531.90, 531.92, 531.95, 532.90, 533.90, 534.90, 535.01, 784.59, 785.79; ICD-10 = K25.0, K25.2, K25.4, K25.6, K26.0, K26.2, K26.4, K26.6, K27.0, K27.2, K27.4, K27.6, K28.0, K28.2, K28.4, K28.6, K29.0, K92.0-2), or diagnosed with a medical condition predisposing to GI bleeding (N = 524, 2%), *i.e.*, alcoholism (ICD-8 = 303; ICD-10 = F10), esophageal varices (IDC-8 = 456.00-09; ICD-10 = I85, I98.2), Mallory-Weiss syndrome (ICD-8 = 530.97; ICD-10 = K22.6), or liver cirrhosis (ICD-8 = 571, 573; ICD-10 = K70, K72-74, K76) (22). Another predisposing condition is cancer, so a further 1,651 (5%) subjects were excluded after linkage with the Danish Cancer Registry (25) because they had a cancer diagnosis after 1980 (all cancer types except nonmelanoma skin cancer) and before the first aspirin prescription. This restriction was made to avoid confounding from these conditions. The size of our study material did not allow analyses within the subgroups of predisposing conditions. Thus, a total of 27,694 (89.5%) users of low-dose aspirin were included in the study cohort.

Person-Years at Risk

The follow-up for hospitalization of upper GI bleeding began at the date of the first notified prescription of low-dose aspirin (100 or 150 mg), and ended at the date of a first admission to hospital for a GI bleeding or for one of the medical conditions that predispose to GI bleeding (alcoholism, esophageal varices, Mallory-Weiss syndrome, liver cirrhosis, or cancer), the date of death, or December 31, 1995, whichever occurred first. The follow-up period of cohort members was then subdivided into periods of current exposure to low-dose aspirin, lasting from the date of prescription until 90 days thereafter (or a censoring date), and periods of no exposure extending from 90 days after a prescription to the date of next prescription (or a censoring date). The period of 90 days was chosen because low-dose aspirin is mainly prescribed in packets for 3-month use. Furthermore, "exposure" and "no exposure" time segments were flagged if cohort members received prescriptions at the same time of one or more other drugs suspected to cause GI bleeding, *i.e.*, high-dose aspirin, other NSAIDs, vitamin K antagonists, or oral corticosteroids, again applying the 90-day rule. Periods of low-dose aspirin use, to which all 27,694 persons contributed follow-up time, were further divided into time segments of "only low-dose aspirin" use (n = 26,196), time segments of combined low-dose aspirin and other NSAID use (n = 10,021) and time segments of exposure to low-dose aspirin in combinations with one of the remaining drugs (n = 3,976). In addition, periods of "only low-dose aspirin" use were further subdivided into enteric-coated aspirin use (n = 6,071) and non–enteric-coated aspirin use (n = 22,678) and into use of 100 mg tablets (n = 6,084) and 150 mg tablets (n = 22,671).

In a subanalysis, we restricted the cohort to 17,328 persons who had no record of a prescription for one of the other drugs mentioned in the present study before receiving the first prescription for low-dose aspirin. For these persons, we investigated the risk of upper GI bleeding during periods of low-dose aspirin use only *versus* subsequent periods after cessation of low-dose aspirin (and no use of any of the drugs), *i.e.*, for current *versus* former use of low-dose aspirin. In all, 84% of the restricted cohort contributed follow-up time to the latter time segments.

Standardized Incidence Ratios

The number of upper GI bleedings observed among cohort members allocated to the appropriate exposure category was

Table 1. Descriptive Characteristics of the Study Cohort of Users of Low-Dose Aspirin in the County of North Jutland, Denmark, 1991–1995

Characteristics	No. of Users	(%)	Person-Years of Follow-Up				
			Current Aspirin Use				
			Aspirin Only	Aspirin and Other NSAIDs*	Aspirin and Other Drugs†	Total Use	Former Use
Total cohort	27,694	(100)	34,560	5,716	1,778	42,054	24,738
Women (yr)	13,865	(50)	16,915	3,327	904	21,146	12,594
16–59	1,979	(7)	1,878	353	74	2,304	1,828
60–69	3,158	(11)	3,675	591	184	4,449	2,688
70+	8,728	(32)	11,362	2,384	646	14,393	8,078
Men (yr)	13,829	(50)	17,645	2,389	874	20,907	12,144
16–59	2,980	(11)	3,124	381	119	3,624	2,675
60–69	3,916	(14)	5,001	566	214	5,782	3,241
70+	6,923	(25)	9,519	1,441	541	11,501	6,227
Coated aspirin‡	6,071§		6,593				
Noncoated aspirin‖	22,678#		27,966				

* Low-dose aspirin and other NSAIDs alone or in combination with one of the other three drugs.
† Low-dose aspirin and high-dose aspirin on prescription, vitamin K antagonists, or oral corticosteroids, but without other NSAIDs.
‡ Person-year contributed by 6,071 persons with periods of coated aspirin use only.
§ Of these, 1,752 persons had used noncoated aspirin only during other periods.
‖ Person-year contributed by 22,678 persons with periods of noncoated aspirin use only.
Of these, 1752 persons had used coated aspirin only during other periods.

compared with the number of cases expected on the basis of the hospitalization rates of upper GI bleeding of North Jutland, and the standardized incidence rate ratio (SIR) was calculated as the ratio of the observed to the expected number of upper GI bleeding. The SIR is a rate ratio in which the incidence rate in the cohort is compared with reference rates while adjusting for age, sex, and calendar time distribution of person-years in the cohort.

County-specific incidence rates per 100,000 person-years of follow-up for a hospitalization for a first upper GI bleeding, calculated according to sex, 5-yr age groups, and 1-yr calendar periods, were applied to the person-years of observation to obtain the number of upper GI bleedings expected had the cohort members experienced the same hospitalization rates for this condition as the general population of the county. To match the definition of an upper GI bleeding of interest that was applied to the study cohort, we calculated the population rates of upper GI bleeding after excluding from the population the inhabitants of the county who were previously hospitalized with GI bleeding, or a medical condition predisposing to GI bleeding (alcoholism, esophageal varices, Mallory-Weiss syndrome, liver cirrhosis, or cancer) or who received a prescription for one of the drugs that may possibly cause GI bleeding.

Finally, tests of significance and confidence intervals (CI) for the SIR were based on the assumption that the observed number of cases in a category followed a Poisson distribution.

RESULTS

During the study period, the 27,694 users of low-dose aspirin contributed a total of 42,054 person-years of observation for current use and 24,738 person-years after cessation of low-dose aspirin use (former users) (Table 1). A total of 85% had received more than one prescription for low-dose aspirin. Approximately 82% of these person-years were derived from low-dose aspirin use only, 14% from combined use of low-dose aspirin and other NSAIDs, and 4% from time segments of combined use of low-dose aspirin and corticosteroids, vitamin K antagonists, or high-dose aspirin. About 50% of the users were women.

In the population of North Jutland during the same period of time, we observed a total of 2,475 first time hospitalizations with upper GI bleeding, corresponding to an overall yearly incidence rate of 126 per 100,000 persons aged ≥16 yr (Table 2). Of these, 471 (19%) occurred in individuals with a medical condition predisposing to GI bleeding, 308 (12%) in individuals with current use of low-dose aspirin, and 892 (36%) in former users of low-dose aspirin and individuals with use of other drugs suspected to induce ulcer (namely, high-dose aspirin, other NSAIDs, vitamin K antagonists, and corticosteroids), leaving a total of 804 (33%) cases of GI bleeding in the population of North Jutland, 1991–1995. This corresponds to an incidence rate of 59.0 cases of bleeding per 100,000 individuals in the remaining population of the county (Table 2).

The SIR for GI bleeding among current users of low-dose aspirin (165 cases among men and 143 among women) was 3.1 (3.0 in men and 3.2 in women) (Table 3). The overall and age-specific risks for bleeding were substantially higher during combined use of low-dose aspirin and other NSAIDs (overall SIR, 5.6), than those observed during use of low-dose aspirin alone (overall SIR, 2.6) and during use of low-dose aspirin in combination with other drugs apart from NSAID (overall SIR, 4.7) (Table 3). The risk estimates among women with combined use of low-dose aspirin and other NSAIDs tended to be higher than among men

Table 2. Number (Obs) of First Hospitalizations for Upper Gastrointestinal Bleeding in Defined Segments of the Population of the County of North Jutland, Denmark, 1991–1995: Incidence Rate for a Subset of the County Population Not Exposed to Specific Drugs and Without Predisposing Conditions

County of North Jutland	County Population		Predisposed Inhabitants*†		Users of Low-Dose Aspirin†		Users of Other Specific Drugs and Former Users of Low-Dose Aspirin†‡		Remaining Population		
Approx. size of populations§	393,800		27,200		27,700		158,500		272,700		
Sex and age (yr)	Obs	(%)	Obs	(%)	Obs	(%)	Obs	(%)	Obs	(%)	IR‖
Both sexes	2,475	(100)	471	(19)	308	(12)	892	(33)	804	(33)	59
Women (yr)	1,154	(100)	174	(15)	143	(12)	514	(45)	323	(28)	48.3
16–59	211	(100)	51	(24)	1	(0.4)	79	(37)	80	(38)	15.4
60–69	164	(100)	32	(20)	17	(10)	65	(40)	50	(30)	71.4
70+	779	(100)	91	(12)	125	(16)	370	(48)	193	(25)	247.4
Men (yr)	1,321	(100)	297	(22)	165	(12)	378	(29)	481	(36)	69.2
16–59	430	(100)	134	(31)	8	(2)	103	(24)	185	(43)	32.6
60–69	221	(100)	53	(24)	28	(13)	57	(26)	83	(38)	124.1
70+	670	(100)	110	(16)	129	(19)	218	(33)	213	(32)	356.6

* Category includes individuals with hospitalization for alcoholism, esophageal varices, Mallory-Weiss syndrome, liver cirrhosis, or cancer.
† The groups overlap partially.
‡ High-dose aspirin on prescription, other NSAIDs, vitamin K antagonists, oral corticosteroids, and former use of low-dose aspirin.
§ Population ≥16 yr of age.
‖ Incidence rate per 100,000 person-years.
Obs = observed.

Table 4 shows the risk of upper GI bleeding during periods with use of low-dose aspirin only, when time segments were further subdivided into periods of enteric-coated (4,178 person-years accumulated) and non–enteric-coated use (18,003 person-years). The risk was similar for non-coated aspirin (SIR = 2.6) and coated tablets (SIR = 2.6). When combined with other NSAIDs, the SIR associated with enteric-coated aspirin, based on nine observed cases, was 3.7 (95% confidence interval [CI], 1.7–7.0), and the corresponding estimated equivalent SIR with noncoated aspirin, based on 71 observed cases, was 6.0 (4.7–7.5) (data not shown). The risk was similar for users of tablets of 100 mg (SIR, 2.6 [1.8–3.5]) and 150 mg (SIR, 2.6 [2.2–3.0]).

In the restricted cohort of persons who had never received a prescription for other NSAID drugs or non-NSAID medication before receiving the first prescription for low-dose aspirin, 137 cases of upper GI bleeding were observed during periods of low-dose aspirin use only, which was 2.7 times more than expected (95% CI, 2.3–3.2). During periods of former use of low-dose aspirin among these persons, 45 cases of upper GI bleeding were seen, yielding a SIR of 1.7 (95% CI, 1.2–2.3). The risk was increased during the year after discontinuation of treatment, when a total of 37 cases was observed (SIR, 1.8; 95% CI, 1.3–2.5), whereas the risk was quite close to unity beyond the first year (SIR, 1.3; 95% CI, 0.6–2.5).

The absolute risk of upper GI bleeding in only users of low-dose aspirin was 364 per 100,000. Under the assump-

Table 3. Standardized Incidence Ratios (SIRs) of Upper Gastrointestinal Bleeding Among 27,694 Current Users of Low-Dose Aspirin in the County of North Jutland, Denmark, 1991–1995

	Low-Dose Aspirin											
Sex and Age (yr) of Cohort Members	Total, Any Current Use				Aspirin Only			Aspirin and Other NSAIDs			Aspirin and Other Drugs		
	Obs	Exp	SIR	95% CI	Obs	SIR	95% CI	Obs	SIR	95% CI	Obs	SIR	95% CI
Both sexes	308	99.8	3.1	2.8–3.4	207	2.6	2.2–2.9	80	5.6	4.4–7.0	21	4.7	2.9–7.2
Women (yr)	143	45.1	3.2	2.7–3.7	82	2.3	1.8–2.9	52	6.9	5.2–9.1	9	4.6	2.1–8.7
16–59	1	0.8	1.3	0.0–7.0	1	1.5	0.0–8.5	0			0		
60–69	17	3.4	5.0	2.9–8.1	7	2.5	1.0–5.2	8	17.9	7.7–35.2	2	15.0	1.7–53.1
70+	125	41.0	3.1	2.5–3.6	74	2.3	1.8–2.9	44	6.3	4.6–8.5	7	3.9	1.5–8.0
Men (yr)	165	54.7	3.0	2.6–3.5	125	2.8	2.3–3.3	28	4.1	2.7–6.0	12	4.9	2.5–8.5
16–59	8	2.6	3.1	1.3–6.0	7	3.1	1.3–6.4	1	3.5	0.0–19.6	0		
60–69	28	7.8	3.6	2.4–5.2	24	3.6	2.3–5.3	2	2.6	0.3–9.5	2	7.0	0.8–25.1
70+	129	44.3	2.9	2.4–3.5	94	2.6	2.1–3.2	25	4.4	2.8–6.4	10	4.8	2.3–8.8

Table 4. Standardized Incidence Ratios (SIRs) of Upper Gastrointestinal Bleeding Among Cohort Members During Periods With Use of Low-Dose Aspirin Only, Stratified by Type of Tablet (Coated *vs* Noncoated)

Type of Tablet	Obs	Exp	SIR	95% CI
Coated aspirin				
Both sexes	38	14.9	2.6	1.8–3.5
Women	15	6.5	2.3	1.3–3.8
Men	23	8.4	2.8	1.7–4.1
Noncoated aspirin				
Both sexes	169	66.2	2.6	2.2–3.0
Women	67	29.1	2.3	1.8–2.9
Men	102	37.0	2.8	2.2–3.3

Obs = observed; Exp = expected.

tion that the association between low-dose aspirin and upper GI bleeding is causal, low-dose aspirin was responsible for an extra 153.2 upper GI bleedings in the exposed population, contributing 42,054 person-years (current users of low-dose aspirin). This means that 6.2% of all GI bleedings (n = 2,475) occurring in North Jutland county over the study period were due to the use of low-dose aspirin.

DISCUSSION

Exposure to low-dose aspirin was associated with an increased risk of admission to the hospital for upper GI bleeding, and low-dose aspirin seems to account for a non-negligible proportion of all upper GI bleeding in the population over the study period. Although the relative risk associated with low-dose aspirin did not vary by age, the substantially higher underlying rates of GI bleeding among the elderly resulted in nearly all aspirin-associated bleeding occurring after age 60 yr. The risk was dose-independent and increased further when aspirin use was combined with exposure to other NSAIDs.

The study is consistent with three recent reports from case-control studies in which odds ratios were raised for all dose levels of aspirin, with odds ratios for low-dose aspirin varying between 2.2 and 3.4 (10–12). By contrast, randomized trials of low-dose aspirin have given mixed results (5, 7–9). Some studies did not report episodes or differences in GI bleeding, whereas others found more episodes in persons exposed to prophylactic aspirin than to placebo, although differences in definition and detection of GI bleeding hinder comparison of the trial results. Randomized trials and case-control studies have strengths, but also limitations. Randomized trials may provide unbiased estimates, but the restriction criteria of the study populations may limit the generalizability (14–16) and have so far included small numbers of events of GI bleeding. Case-control studies may be affected by biased or differential recall or reporting of prior analgesic use among case and control subjects.

Secondary prophylactic use of low-dose aspirin in Denmark during 1991–1995 primarily involved prescriptions of 100 or 150 mg noncoated tablets for daily consumption. Endoscopic studies indicate that enteric-coated aspirin has a lower risk of gastric erosion and microbleeding (26–28). Although <20% of users took coated products, our results suggest that enteric-coated, low-dose aspirin may have no substantially reduced risk of upper GI bleeding, and the risk estimates correspond well with those of a recent case-control study in the United States (12). Newer low-dose products typically involve doses <100 mg in enteric-coated form. We could not evaluate the risk of GI bleeding among such users, but found no difference in the risk for use of 100-mg and 150-mg tablets. NSAIDs are among the most commonly prescribed drugs and, because of their frequent use, they often coincide with low-dose aspirin. The risk of combined low-dose aspirin and other types of NSAIDs seems to be at the same level as NSAID treatment alone (20, 29).

The main strengths of our study are its large size, the uniformly organized health care system allowing a population-based design (thus avoiding selection bias introduced by differential patient recruitment), our ability to adjust for intake of other drugs and conditions predisposing to GI bleedings, and the completeness of follow-up. However, our study did not allow analyses of the subgroups of patients with predisposition conditions.

The weaknesses include our inability to control for smoking, alcohol intake, and infection with *Helicobacter pylori*. All nonaspirin NSAIDs are only available by prescription, except low-dose ibuprofen, which is obtainable over the counter in Denmark. However, regular users of low-dose ibuprofen are registered in our database, as they receive a 50% refund when redeeming a prescription for ibuprofen. Users of low-dose aspirin also receive a 50% refund if they have a prescription. Therefore, we have probably registered most of the patients receiving low-dose aspirin and NSAID on a regular basis. We also could not control for over-the-counter use of 500-mg aspirin tablets that were not prescribed by physicians. However, we have no reason to believe that over-the-counter use of aspirin or ibuprofen occurred more often among cohort members that it did in our comparison group of persons not having prescriptions for low-dose aspirin or the other drugs suspected of causing upper GI bleeding. We assume that most of the uncaptured use of aspirin will be outside the low-dose aspirin cohort members, as they will get their drug cost refunded. Thus

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