Table 2.7. Cohort studies of tamoxifen use and gastrointestinal cancers

Reference, location, name of study	Cohort description	Exposure assessment	Exposure categories	No. of cases of gastrointestinal cancers	Relative risk 95% CI	Comments
Curtis et al. (1996), United States	Cohort of 87 323 women reported to the US SEER Program diagnosed with early-stage (localized or regional) breast cancer between 1980 and 1992, aged at least 50 years at diagnosis who had not been given chemotherapy as an initial treatment, mean follow-up of [4.4] years	The SEER database indicated that 14 358 had received hormonal therapy (which for over 90% was tamoxifen treatment) and 72 965 had not.	Tamoxifen use	All digestive system:	SIR	Expected rates relative to the general SEER population
			Yes	153	1.02 (0.86–1.19)	
			No	1186	0.93 (0.87–0.98)	
				Oesophagus		
			Yes	6	1.49 (0.54–3.24)	
			No	38	1.11 (0.78–1.52)	
				Stomach:		
			Yes	15	1.23 (0.69–2.03)	
			No	118	1.13 (0.93–1.35)	
				Colon:		
			Yes	80	1.04 (0.83–1.30)	
			No	613	0.94 (0.87–1.02)	

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Newcomb et al. (1999), United States	Cohort of 85 411 women with local or regional breast cancer diagnosed from 1983–90, followed to December 31, 1994	Reported as receiving hormonal therapy at the time of initial registration. 14 984 women received hormonal therapy (nearly all tamoxifen) and 70 427 did not.	Tamoxifen use	Stomach:	SIR	Expected rates from SEER incidence rates Risks not reported for all gastrointestinal cancers; adjusted for age, race, stage, registry site, year of diagnosis, tumour size and treatment (radiation/chemotherapy)
			Overall			
			No	73	1.0 (ref)	
			Yes	19	1.09 (0.63–1.88)	
			5+ years after			
			No	21	1.0 (ref)	
			Yes	5	1.46 (0.51–4.20)	
			Overall	Colorectal:		
			No	591	1.0 (ref)	
			Yes	123	1.09 (0.88–1.35)	
			5+ years after			
			No	198	1.0 (ref)	
			Yes	40	1.47 (1.00–2.15)	

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Matsuyama et al. (2000), Japan	Retrospective cohort study of 6 148 women treated for breast cancer during 1982–90 in nine institutions in Japan.	Medical records or a prospectively compiled computer database at each institution. 3 358 women received tamoxifen, mainly for 2 years or less, and were followed for a mean of 7.64 years, 2 560 women did not receive tamoxifen and were followed for 8.10 years.			Incidence rate ratio	The SIR for stomach cancer in the tamoxifen-treated group compared to the general population was 1.49 (P = 0.01).
				Oesophagus:		
			No	1	1.0 (ref)	
			Yes	1	0.73 (0.05–11.7)	
				Stomach:		
			No	19	1.0 (ref)	
			Yes	32	1.34 (0.76–2.38)	
				Colorectal:		
			No	18	1.0 (ref)	
			Yes	21	0.91 (0.49–1.72)	
Srinivasan et al. (2005), United Kingdom	Retrospective cohort study based upon the General Practitioner Research Database of the United Kingdom. The study included 17 415 breast cancer patients and 69 660 matched control patients without a prior history of breast cancer with follow-up time of 52 914 and 331 480, person-years respectively	Information on tamoxifen use from the General Practitioner Research Database (84.9% breast cancer patients received tamoxifen, 0.3% of matched controls)		Colorectal	Rate ratio	Only colorectal cancer data reported. Rates compared to the compared to the rate in women without a history of breast cancer. Rates similar if first 6 months of follow-up excluded.
			No	NR	1.34 (0.63–2.84)	
			Yes	NR	0.73 (0.49–1.08)	

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Reference, location, name of study	Cohort description	Exposure assessment	Exposure categories	No. of cases of gastrointestinal cancers	Relative risk 95% CI	Comments
Chandanos et al. (2006), Sweden	Population-based cohort study of all women aged over 50 years with breast cancer in the Swedish Cancer Register in 1961–2003. Follow-up was by record linkage within the Cancer Register and the Registers of Death and Emigration. 138 885 cohort members contributed 1 075 724 person-years of follow-up,	Those diagnosed before 31 December 1987 were regarded as unexposed to tamoxifen, whereas those diagnosed after that date were considered potentially exposed.	Tamoxifen exposure	Oesophageal adenocarcinoma	SIR	Expected number of cases calculated by multiplying the observed number of person-years by age-specific and calendar year-specific incidence rates, in 5-year intervals, from the Swedish female population. The SIR for non-cardia gastric adenocarcinoma was 1.86 in the potential tamoxifen period in the period of longest latency (10–14 years) (95% CI: 1.10–3.14, based on 14 cases). The SIR did not increase with longer latency intervals in the unexposed group.
			Unexposed (1961–1987)	10	1.17 (0.63–2.18)	
			Exposed (1988–2003	9	1.60 (0.83–3.08)	
				Gastric cardia adenocarcinoma		
			Unexposed (1961–1987)	12	0.75 (0.42–1.32)	
			Exposed (1988–2003	9	0.96 (0.50–1.86)	
				Gastric non- cardia adenocarcinoma		
			Unexposed (1961–1987)	257	1.47 (1.30–1.66)	
			Exposed (1988–2003	84	1.27 (1.03–1.57)	