

# Vasectomy and Prostate Cancer: A Case-Control Study in India

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**Background.** The role of vasectomy in the development of prostate cancer remains controversial. In particular, there has been concern about detection bias and confounding in the previously published epidemiological studies examining this hypothesis. With the goal of minimizing detection bias, we have evaluated the relation between vasectomy and prostate cancer in a population without routine prostate cancer screening.

**Methods.** A case-control study consisting of 175 prostate cancer cases and 978 controls with cancer diagnoses other than prostate cancer was conducted at hospitals covered by the Bombay Cancer Registry in Bombay, India. History of vasectomy, demographic, and lifestyle factors were obtained by structured interview. Multiple logistic regression was used to estimate odds ratios (OR) and 95% confidence intervals (CI).

**Results.** Standardizing by age, 8.7% of cases and 8.3% of controls had had a vasectomy. The OR for prostate cancer comparing men who had had a vasectomy to those who did not was 1.48 (95% CI : 0.80–2.72) controlling for age at diagnosis, smoking status, alcohol drinking, and other demographic and lifestyle factors. Risk of prostate cancer associated with vasectomy appeared to be higher among men who underwent vasectomy at least two decades prior to cancer diagnosis or who were at least 40 years old at vasectomy.

**Conclusions.** Although not statistically significant, the results of this hospital-based case-control study are consistent with the hypothesis of a positive association between vasectomy and prostate cancer. Because routine prostate cancer screening is not common in this population, detection bias was unlikely to account for this association.

**Keywords:** prostate cancer, vasectomy, case-control study, India

Vasectomy is used world wide for contraception. It is effective and has few acute or long-term untoward effects.<sup>1–3</sup> There has been concern over a positive association between vasectomy and prostate cancer since the late 1980s when Honda *et al.* first reported findings from their population-based case-control study.<sup>4</sup> This relation remains controversial, with some studies reporting a positive<sup>4–11</sup> and others no association.<sup>12–17</sup>

Two main criticisms of those studies purporting an association are that detection bias or confounding may have produced a spurious association between vasectomy and prostate cancer.<sup>18,19</sup> For example, detection bias might have arisen if those who underwent vasectomy were more likely to have repeated medical contact with greater opportunity for screening, and thus, detection of asymptomatic prostate cancer. Confounding might have gone unnoticed because the majority of the positive

studies published to date have been conducted in the US, where those dietary and lifestyle factors that potentially confound the relation between vasectomy and prostate cancer may be operating similarly in each study.

In India, vasectomy has been practiced since the 1950s following ongoing promotion by the National Family Planning Programme.<sup>20</sup> It is estimated that 13 million Indian men have had a vasectomy and that 7% of all married couples in the reproductive age group use vasectomy as a method of contraception.<sup>21</sup> The majority of these men underwent the procedure by the late 1970s and now are entering the age range of greatest prostate cancer risk.<sup>21</sup>

In this paper, we report the findings of a hospital-based case-control study of vasectomy and prostate cancer conducted in India, where detection bias is unlikely because screening for prostate cancer is not routine, the incidence of prostate cancer is low (6.9 in Bombay, India versus 61.8/100 000 per year in US whites, standardized to the world age distribution<sup>22</sup>), and the distribution of identified and unidentified potential confounders of the association between vasectomy and prostate cancer likely differs from those in North America and Europe.

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## METHODS

### *Population and Measurements*

Cases were all patients  $\geq 40$  years of age with newly diagnosed prostate cancer admitted to the Tata Memorial Hospital or to any other hospital of Bombay covered by the Cancer Registry between 1 July 1993 and 30 June 1994 ( $N = 175$ ). Patients admitted to hospitals other than Tata Memorial were included only if they were Bombay residents. Controls were all male patients with newly diagnosed cancer of the oesophagus (31.9%); larynx (26.8%); lip, oral cavity, or pharynx (22.6%); or colon, rectum, or anus (18.7%) admitted to the same hospitals over the same time period as the cases and satisfying the same age and residency requirements ( $N = 978$ ).

The study was conducted taking advantage of the mechanisms for case detection, collection of information, data entry, and analyses of the Bombay Cancer Registry. The Bombay Cancer Registry, established in 1963, was the first population-based registry to be organized in India. This registry restricts its coverage to the resident population of Greater Bombay. Since its inception, efforts have been made to register all residents of the city suffering from cancer. The details regarding registration have been described in previous publications.<sup>23,24</sup> The data reported by the Bombay Cancer Registry have been shown to be complete and reliable.<sup>25</sup>

As part of the routine operation of the Registry, medical social workers visit the major city hospitals every week and review information on new admissions to detect patients with cancer. Those patients who live within the area covered by the Registry are interviewed in the hospital and the information on cancer is recorded on a structured questionnaire. Information on date of diagnosis, tumour histology and stage, as available is recorded. For the purposes of the present study, we complemented this information with a supplementary questionnaire that included specific questions on vasectomy. In addition, to increase the number of cases, we extended the investigation to include all eligible patients admitted to the Tata Memorial Hospital the main oncological hospital in Bombay. Overall response rates were 93% for cases and 95% for controls. Of the prostate cancer cases, 79.4% were histologically confirmed.

### *Statistical Analysis*

To account for an older age distribution among cases, means and proportions for demographic and lifestyle factors characterizing the cases and controls were directly standardized to the age distribution of cases and controls combined.<sup>26</sup> Age-adjusted, age- and smoking-adjusted, and multivariate odds ratios (OR) were estimated using logistic regression and corresponding

95% confidence intervals (CI) were calculated.<sup>27</sup> In these analyses 5-year age categories were used in all logistic models. Results of analyses with finer age categorization (e.g. 2-year intervals) or modelling age as a continuous variable were virtually identical and are not reported. Because smoking was likely to be over represented among the cancer controls, *a priori* we adjusted for smoking status (never, past, current cigarette smoker only, current beedie smoker only, current cigarette and beedie smoker, unknown status), to avoid a spurious association that might arise if the distribution of smoking status also differed by vasectomy status. In addition to age and smoking status, other demographic or lifestyle factors were included in the multivariate models if the age-standardized distribution appeared to differ by case status, and by vasectomy status among the controls. These were: alcohol drinking (none,  $< 5$ /week,  $\geq 5$ /week, unknown status), employment status, marital status (unmarried, currently married), education ( $<$ grade school,  $\geq$ grade school), religion (Hindu, all others), language spoken (other, Marathi), residence (other, State of Maharashtra), rural area (urban, rural), previous residence (other, State of Maharashtra), and monthly family income (Rupees). To determine whether risk of prostate cancer associated with vasectomy varied by time since vasectomy or age at vasectomy, we chose cut points ( $< 20$  or  $\geq 20$  years ago and  $< 40$  and  $\geq 40$  years old) that were used previously in the literature. All analyses were conducted using SAS.<sup>28</sup>

## RESULTS

The study population consisted of 175 prostate cancer cases and 978 controls. Of these, 17 cases and 83 controls reported a history of vasectomy. Cases were older at diagnosis (Table 1). Standardizing by age, cases and controls were similar on most demographic factors, although consistent with having a cancer diagnosis, controls were more likely to be smokers and drinkers (Table 1). Among controls, those who underwent vasectomy were more likely to be smokers (Table 2). Controls with or without vasectomy were similar across a variety of demographic factors.

Controlling for age, the OR for prostate cancer comparing vasectomy to none was 1.31 (95% CI : 0.74–2.33). The association between vasectomy and prostate cancer was somewhat strengthened after further adjusting for smoking status (RR = 1.45, 95% CI : 0.80–2.64) or multiple covariates, including age, smoking status, alcohol drinking, employment status, marital status, education, religion, language spoken, residence, living in a rural area, previous residence, and income

TABLE 1 Age-standardized characteristics of cases and controls

	Control (n = 978)	Case (n = 175)
Age (mean)	59.1	67.3
Vasectomy (%)	8.3	8.7
Employed (%)	51.0	38.1
Married (%)	85.7	87.4
Completed grade school (%)	61.1	60.7
Religion (% Hindu)	82.3	79.9
Language spoken (% Marathi)	33.0	30.0
State of birth (% Maharashtra)	40.9	39.1
State of residence (% Maharashtra)	59.3	60.4
Living in rural area (%)	35.4	19.5
Previous residence (% Maharashtra)	42.2	53.8
Vegetarian (%)	30.4	32.4
Smoker (%)	47.0	19.6
Alcohol drinker (%)	20.5	16.5
Monthly family income in Rupees (mean)	2064.5	2620.2
Number of children (mean)	4.0	4.5

TABLE 2 Age-standardized relation of selected variables to vasectomy among controls

	No vasectomy (n = 895)	Vasectomy (n = 83)
Age (mean)	59.2	58.7
Employed (%)	54.9	48.3
Married (%)	86.2	93.9
Completed grade school (%)	61.7	57.4
Religion (% Hindu)	82.3	84.5
Language spoken (% Marathi)	31.5	44.6
State of birth (% Maharashtra)	39.5	53.2
State of residence (% Maharashtra)	58.6	64.1
Living in rural area (%)	35.7	30.9
Previous residence (% Maharashtra)	41.0	53.7
Vegetarian (%)	30.4	31.2
Smoker (%)	47.0	64.2
Alcohol drinker (%)	20.5	33.7
Monthly family income in Rupees (mean)	2020.2	2143.5
Number of children (mean)	3.9	4.2

(RR = 1.48, 95% CI : 0.80–2.72) (Table 3). Based on only 39 cases, the age-adjusted OR for prostate cancers that were metastatic (i.e. lymph node involvement or distant metastasis) at diagnosis was 2.58 (95% CI : 1.00–6.65).

Risk of prostate cancer varied by time since vasectomy. Compared to men without a vasectomy, men who underwent vasectomy >20 years previously had 1.56 times the risk of prostate cancer (95% CI : 0.79–3.08),

while those who had a vasectomy within the last 20 years had 1.25 times the risk (95% CI : 0.35–4.40) in multivariate analysis. Risk of prostate cancer also varied by age at vasectomy. Compared to men without a vasectomy, for men who were ≥40 years old at vasectomy, the OR was 2.10 (95% CI : 1.02–4.31), while the OR for men who underwent vasectomy under age 40 was not elevated (RR = 0.77, 95% CI : 0.26–2.33) (Table 4).

DISCUSSION

In this case-control study conducted in Bombay, India, we found a non-statistically significant 50% increased risk of prostate cancer among men who had had a vasectomy compared to men without a vasectomy. Risk of prostate cancer associated with vasectomy appeared to be higher among men who underwent vasectomy at least two decades prior to cancer diagnosis or who were older at vasectomy.

There are several strengths of this study. Cases and controls were drawn from a population in India where screening for prostate cancer is not customary; and most cases were symptomatic at diagnosis. As part of an Indian government programme to curtail fertility during the 1960s and 1970s vasectomies were performed in specially dedicated clinics and camps with incentives given to men accepting this form of contraception.<sup>20,29,30</sup> Thus, the distribution of unidentified socioeconomic or behavioural risk factors for prostate cancer between men with and without vasectomy is likely to be quite different in this population than in the previously studied Western countries. Only three studies to date have included sizeable samples of men other than whites of European heritage: Chinese,<sup>5</sup> African-American,<sup>7,13</sup> and Asian-American.<sup>13</sup> Every effort was made to ensure that cases and controls were drawn from the same source population; all subjects were Bombay residents with newly diagnosed prostate cancer, if a case, or oesophageal, laryngeal, lip, oral cavity, pharyngeal, colorectal, or anal cancer, if a control, during the same time period. The Bombay Cancer Registry, the oldest registry in India, and which has established mechanisms for case-ascertainment, interview, and analysis, was used to identify subjects rapidly. Trained interviewers who are full-time employees of the Registry conducted the interviews.

Although this study may be viewed as limited by having a control group consisting of other cancer cases, vasectomy is unlikely to be related to cancers of these other sites.<sup>2,12</sup> To limit confounding that might result because other lifestyle factors that are determinants of cancer risk may be over represented among these

TABLE 3 Odds ratio (OR) for prostate cancer by vasectomy status and years since vasectomy

	No vasectomy	Vasectomy <20 years ago	Vasectomy 20+ years ago	Total vasectomy
No. of cases	158	3	14	17
No. of controls	895	32	50	83 <sup>a</sup>
Adjusted by age				
OR	1.00	0.81	1.54	1.31
95% CI	–	(0.23–2.78)	(0.81–2.93)	(0.74–2.33)
Adjusted by age and smoking status				
OR	1.00	1.20	1.54	1.45
95% CI	–	(0.34–4.22)	(0.79–2.99)	(0.80–2.64)
Adjusted by multiple covariates <sup>b</sup>				
OR	1.00	1.25	1.56	1.48
95% CI	–	(0.35–4.40)	(0.79–3.08)	(0.80–2.72)

<sup>a</sup> One missing year of vasectomy.

<sup>b</sup> Age (5-year intervals), smoking status (never, past, current cigarette smoker only, current beedie smoker only, current cigarette and beedie smoker, unknown status), alcohol drinking (none, <5/week, ≥5/week, unknown status), employment status, marital status (unmarried, currently married), education (<grade school, ≥grade school), religion (Hindu, all others), language spoken (other, Marathi), residence (other, State of Maharashtra), rural area (urban, rural), previous residence (other, State of Maharashtra), monthly family income (Rupees).

TABLE 4 Odds ratio (OR) for prostate cancer by age at vasectomy

	Age at vasectomy		
	No vasectomy	<40 years	40 years
No. of cases	158	4	13
No. of controls	895	41	41
Adjusted by age			
OR	1.0	0.78	1.70
95% CI	–	(0.26–2.28)	(0.87–3.33)
Adjusted by age and smoking status			
OR	1.0	0.75	2.08
95% CI	–	(0.25–2.23)	(1.02–4.23)
Adjusted by multiple covariates <sup>a</sup>			
OR	1.0	0.77	2.10
95% CI	–	(0.26–2.33)	(1.02–4.31)

<sup>a</sup> Age (5-year intervals), smoking status (never, past, current cigarette smoker only, current beedie smoker only, current cigarette and beedie smoker, unknown status), alcohol drinking (none, <5/week, ≥5/week, unknown status), employment status, marital status (unmarried, currently married), education (<grade school, ≥grade school), religion (Hindu, all others), language spoken (other, Marathi), residence (other, State of Maharashtra), rural area (urban, rural), previous residence (other, State of Maharashtra), monthly family income (Rupees).

cancer controls, in the analysis we controlled for factors including smoking status, alcohol consumption, and marital status. Residual confounding by these factors cannot be entirely ruled out, however. In addition to technical convenience, use of cancer patients as the comparison likely diminished biased recall as both cases and controls were hospitalized with a similar and serious disease. Although several of the participants had limited formal education, and vasectomy was self-reported, non-differential misclassification of vasectomy

status, which would tend to attenuate its relation with prostate cancer, is unlikely. In a pilot study of 273 cancer patients and 235 with other diagnoses, interviewers reported that the men appeared to easily understand and report history of vasectomy without reservation. Although limited by a small size, the estimates for vasectomy, as well as, time since vasectomy and age at vasectomy obtained here are remarkably compatible with those reported in two other large study populations.<sup>8,9</sup>

Fourteen epidemiological studies have previously reported results describing the relation between vasectomy and prostate cancer. Among the five hospital-based-case control studies, which were conducted in the US<sup>6,10-12</sup> or China,<sup>5</sup> the relative risk for this relation ranged from 1.2 to 6.7, depending on the control group used (e.g. cancer controls, non-cancer controls, neighbourhood controls). Among the three population-based case-control studies which were conducted in the US<sup>4,7</sup> or in the US and Canada<sup>13</sup> and in which two included non-white individuals,<sup>7,13</sup> the relative risk ranged from 1.1 to 1.4. In a case-control study conducted within a US health maintenance organization the relative risk was 0.86 (95% CI : 0.57-1.32).<sup>17</sup> In four of the cohort studies, two of which were prospective,<sup>9,14</sup> one retrospective,<sup>8</sup> and one linkage,<sup>16</sup> the relative risk ranged from 0.96 to 1.85. An additional retrospective cohort study reported a relative risk of 0.44 based on only six cases of prostate cancer.<sup>15</sup>

Although one population-based case-control study conducted in the US showed an elevated risk of prostate cancer associated with vasectomy only among black, but not white men, among white men or with both races combined risk was greater among those who had their vasectomy more than 20 years ago.<sup>7</sup> Similarly, several other studies have demonstrated that risk of prostate cancer varies by time since vasectomy,<sup>4,6,8,9,11</sup> including the current study, with risk being greater among those who had a vasectomy decades previously, although some saw no variation in risk over time since vasectomy.<sup>10,12-14,16,17</sup>

Whether risk of prostate cancer associated with vasectomy varies by age at vasectomy, has been examined in a few studies; the findings are disparate. As in the current study, in a large retrospective cohort study, a suggestion of a higher risk among men who were over 40 years old at vasectomy was seen,<sup>8</sup> in a population-based case-control study a higher risk among those who were under 35 years old at vasectomy was observed,<sup>7</sup> and in two case-control and one cohort study no clear elevation in risk above or below age 35 or 40 was seen.<sup>13,14,17</sup>

Some have argued that the finding of a positive relation between vasectomy and prostate cancer reflects detection bias or confounding by unmeasured factors.<sup>18,19</sup> As in the only other study conducted in a non-white population outside of the US,<sup>5</sup> we avoided detection bias by evaluating this relation in an unscreened population. Also when we evaluated the relation using only the most severe prostate cancer cases, those which were most likely symptomatic at diagnosis, the OR was greater. Evidence against detection bias accounting for the positive relation in

studies conducted in populations with routine digital rectal examination or prostate-specific antigen (PSA) screening comes from two large US studies, where the relation was evident among those with advanced stage disease, which is more likely to be symptomatic at diagnosis and thus, not subject to factors that dictate presentation for screening.<sup>8,9</sup> Further, the prevalence of rectal examinations did not vary between men with and without a vasectomy; during the time period of that study, before widespread use of PSA testing, rectal examination was by far the most common screening test for prostate cancer.<sup>9</sup>

The observed relation between vasectomy and prostate cancer in this and other studies could be due to confounding by higher testosterone levels, which are thought to promote prostate tumours. Men with higher testosterone levels might be more sexually active and thus, more likely to undergo vasectomy to control fertility. However, having had a vasectomy is unlikely to be strongly correlated with baseline testosterone concentrations in these men because of the population-wide fertility control incentives offered to undergo this procedure.

As bias and confounding likely do not entirely explain the differences in findings between the epidemiological studies of vasectomy and prostate cancer, key study design differences should be considered. Since risk of prostate cancer appears to be greatest among those who had vasectomy at least two decades previously, length of follow-up post vasectomy is an important design feature. Among the null cohort studies, mean time since vasectomy was just under 7 years in two<sup>14,15</sup> and the maximum was 12 years in the third.<sup>16</sup> In the two positive cohort studies, although disease follow-up began in 1976<sup>8</sup> or 1986,<sup>9</sup> more than 40% of the vasectomies among cases had been performed 20 years or longer before cancer diagnosis. In the present study, about 60% of the vasectomies among cases and controls were performed more than 20 years before the interview.

The biological basis underlying the vasectomy-prostate cancer relation remains speculative. Elevations in anti-spermatozoa antibodies, decreased seminal hormone concentrations, and decreased prostatic secretion have been reported by men who underwent vasectomy and in animal models.<sup>8</sup> How these changes potentially mediate prostate carcinogenesis is unknown.

Few strong predictors of prostate cancer, such as older age, black race, and family history, have been established with certainty. High intake of meat or animal fat appears to increase risk, while high intake of the carotenoid lycopene appears to reduce risk.<sup>31</sup> Based on the present study and others, risk of prostate cancer

resulting from vasectomy is comparable in magnitude to the modifiable and modest compared to non-modifiable risk factors.

Noting the limitations, this study conducted among Indian men is consistent with the hypothesis of a positive association between vasectomy and prostate cancer. Only one other study to date has been conducted in a non-white population outside of the US.<sup>5</sup> Because of the importance of vasectomy for fertility control, further studies with long-term follow-up of documented vasectomy in populations where screening for prostate cancer is not routine are needed. These studies should also better characterize men at higher risk (e.g. by time since vasectomy or age at vasectomy).

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