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## Original Research

# Risk of hospitalization and death following prostate biopsy in Scotland



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## ABSTRACT

**Objective:** To investigate the risk of hospitalization and death following prostate biopsy.

**Study design:** Retrospective cohort study.

**Methods:** Our study population comprised 10,285 patients with a record of first ever prostate biopsy between 2009 and 2013 on computerized acute hospital discharge or outpatient records covering Scotland. Using the general population as a comparison group, expected numbers of admissions/deaths were derived by applying age-, sex-, deprivation category-, and calendar year-specific rates of hospital admissions/deaths to the study population. Indirectly standardized hospital admission ratios (SHRs) and mortality ratios (SMRs) were calculated by dividing the observed numbers of admissions/deaths by expected numbers. **Results:** Compared with background rates, patients were more likely to be admitted to hospital within 30 days (SHR 2.7; 95% confidence interval 2.4, 2.9) and 120 days (SHR 4.0; 3.8, 4.1) of biopsy. Patients with prior co-morbidity had higher SHRs. The risk of death within 30 days of biopsy was not increased significantly (SMR 1.6; 0.9, 2.7), but within 120 days, the risk of death was significantly higher than expected (SMR 1.9; 1.5, 2.4). The risk of death increased with age and tended to be higher among patients with prior co-morbidity. Overall risks of hospitalization and of death up to 120 days were increased both in men diagnosed and those not diagnosed with prostate cancer.

**Conclusions:** Higher rates of adverse events in older patients and patients with prior co-morbidity emphasizes the need for careful patient selection for prostate biopsy and justifies ongoing efforts to minimize the risk of complications.

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## Introduction

Screening for prostate cancer using the prostate-specific antigen (PSA) test remains controversial. In a Cochrane review, based on a meta-analysis of five randomized trials, the authors concluded that screening does not reduce prostate cancer-specific and overall mortality; that harms associated with PSA-based screening and subsequent diagnostic evaluations are frequent, and moderate in severity; and that over-diagnosis and over-treatment are common and are associated with treatment-related harms.<sup>1</sup>

Limited information is published on the potential adverse consequences of prostate screening in real world clinical practice compared with appropriate control populations. The aim of this study was to investigate the risk of hospitalization and death following prostate biopsy in a cohort of patients selected from computerized hospital records in Scotland.

## Methods

We performed a retrospective cohort study relating first ever prostate biopsy to hospitalization and/or death within 30 and 120 days. Record linkage was achieved using the Community Health Index number, a unique identifying number used by the National Health Service (NHS) in Scotland. We studied the first biopsy in any individual because the inclusion of every biopsy would result in a complex analysis, and the decision to undertake a subsequent biopsy may be influenced by complications arising after a previous biopsy.

The study population comprised patients with a record of first ever prostate biopsy between 2009 and 2013 inclusive on computerized acute hospital discharge or outpatient records covering the whole of Scotland (total population approximately 5.3 million). Patients were selected on the basis of procedure codes drawn from the fourth revision of the Office of Population Censuses and Surveys Classification of Surgical Operations and Procedures (OPCS-4)<sup>2</sup> (See [Appendix](#)). Endoscopic biopsies of prostate and open biopsies of prostate were not included. Diagnosis of prostate cancer within 120 days before or after prostate biopsy was established from linked Scottish Cancer Registry records.

Socio-economic position is likely to be an important confounding factor because men from less deprived areas of residence are more likely to have a PSA test,<sup>3</sup> but less likely to die from all causes combined. Therefore, the Scottish Index of Multiple Deprivation 2012 was used as a postcode-referenced, small area indicator of socio-economic position.<sup>4</sup> This has seven domains (income, employment, education, housing, health, crime, and geographical access) at 'datazone' level (areas with approximately 500–1000 household residents), which have been combined into an overall index to identify area concentrations of multiple deprivation.

In the context of this study, we sought to assess data quality in two ways. First, for a single region of Scotland (Tayside, total population approximately 414,000), we linked electronic pathology records for prostate biopsy to prostate biopsies on acute hospital discharge and outpatient records

for the period 2009–2013. For this part of the study, we did not restrict the analysis to first biopsies. We determined the proportion of prostate biopsies that were unrecorded on hospital records and, of greater concern, the proportion of prostate biopsies recorded in error on hospital records. Second, for all Scottish patients identified as dying within 30 days of prostate biopsy, we reviewed their archived primary care records (or when these were inadequate, their electronic pathology record) to verify whether they had indeed undergone prostate biopsy within 30 days of death.

For the whole of Scotland, the numbers of prostate biopsies were examined in conjunction with numbers of admissions to hospital (continuous inpatient stays) and numbers of deaths, both within 30 and 120 days. Crude rates of hospitalization and death per 1000 patients were calculated for all patients combined, and also stratified by age group, deprivation fifth, prior co-morbidity, and whether diagnosed with prostate cancer. Reasons for admission to hospital were summarized for all patients combined, and separately for patients diagnosed or not diagnosed with prostate cancer. In particular, we focused on any mention of haemorrhage (e.g. haematuria), infection (e.g. urinary  $\pm$  bacteraemia, rectal abscess), other urinary symptoms (e.g. retention, incontinence) and any mention of invasive procedures (e.g. catheterization). See [Appendix](#) for a detailed list of potentially relevant diagnostic (ICD-10) and procedure (OPCS-4) codes. Two indicators of prior co-morbidity, derived from hospital discharge data, were used: Charlson score based on primary diagnosis,<sup>5</sup> and prior inpatient bed days, both during the five year period immediately before prostate biopsy (but in the case of bed days, excluding the most recent six-month period, which would seem more likely to include some prostate-associated morbidity).

Indirectly standardized hospital admission ratios (SHRs) and mortality ratios (SMRs) were calculated by dividing the observed numbers of admissions/deaths by expected numbers. Again, results were stratified by subgroups, as described above. Both age and co-morbidity have been shown to predict the risk of mortality independently following prostate biopsy in previous research.<sup>6</sup> Follow-up was from date of prostate biopsy to 30/120 days after biopsy, or to date of death, whichever occurred first. For the hospitalization analysis, all continuous inpatient stays were counted. Using the general population as a comparison group, expected numbers of admissions/deaths were derived by applying age-, sex-, deprivation category-, and calendar year-specific rates of hospital admissions/deaths to the study population. Rates were calculated using population data sourced from National Records of Scotland. The 95% confidence intervals (CIs) around SHRs and SMRs were calculated based on the assumption that the observed numbers of admissions/deaths followed a Poisson distribution. SHRs and SMRs with 95% CI that do not include the value 1.0 were regarded as statistically significant.

Finally, for patients who died within 30 days of a prostate biopsy, their original death certificates were reviewed, taking account of the interval between biopsy and death, and the diagnoses listed, to assess whether the prostate biopsy might have contributed to their death.

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