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Original Article

Transrectal ultrasound-guided prostate biopsy in Taiwan: A nationwide database study

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Abstract

Background: For patients with an elevated prostate specific antigen (PSA) level or a suspected lesion detected by digital rectal examination, transrectal ultrasound-guided (TRUS) prostate biopsy is the standard procedure for prostate cancer diagnoses. In Taiwan, TRUS prostate biopsy has not been well-studied on a nationwide scale. This article aimed to study TRUS prostate biopsy in Taiwan and its related complications, according to the claims generated through the National Health Insurance (NHI) program.

Methods: We applied for access to claims from the NHI Research Database of Taiwan of all patients who visited the urology clinic during the period of 2006 to 2010. In the 5-year urology profile, we obtained all records, which included admission and ambulatory clinical records. The definition of TRUS biopsy included codes for ultrasound-guided procedure and for prostate puncture; other codes involving complications such as postbiopsy voiding difficulty, significant bleeding, or infection requiring treatment were also included. Risk factors included age, diagnosis of prostate cancer, hospitalization or nonhospitalization, and the Charlson Comorbidity Index (CCI; with a value of 0, 1, 2 or ≥ 3). Descriptive and comparative analyses were also performed.

Results: In the 5-year urology profile, 12,968 TRUS biopsies performed of which 6885 were in-patient procedures and 6083 were ambulatory clinic procedures. After the procedures, 1266 (9.76%) biopsies were associated with voiding difficulty; 148 (1.14%) biopsies, with significant bleeding; and 855 (6.59%) biopsies, with infection that required treatment. The prostate cancer diagnosis rate was 36.02%. The overall biopsy-related mortality rate within 30 days was 0.25%, and the postbiopsy sepsis-related mortality rate was 0.13%. Age, diagnosis of cancer, hospitalization, and CCI value ≥ 1 were all significant factors in univariate analysis and multivariate analysis for postbiopsy voiding difficulty and severe infection. A diagnosis of cancer and a CCI value ≥ 2 were significant factors for significant bleeding after biopsy. Patients diagnosed as having prostate cancer had fewer bleeding complications after biopsy.

Conclusion: The most frequent complication was postbiopsy voiding difficulty, followed by infection that required treatment and significant bleeding. The sepsis-related mortality rate was 0.13%. Significant risk factors for postbiopsy complications included age, diagnosis of prostate cancer, hospitalization, and the CCI value.

Keywords: complication; National Health Insurance; research database; Taiwan; transrectal ultrasound-guided prostate biopsy

Conflicts of interest: The authors declare that there are no conflicts of interest related to the subject matter or materials discussed in this article.

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1. Introduction

National Health Insurance (NHI) in Taiwan has been in effect since May 1995, and the coverage rate is 99% of the population.[1] Since 1999, the Bureau of the NHI has established two types of databases that are subgroups of the larger National Health Insurance Research Database (NHIRD). One database is the random sampled database comprising ambulatory visits or admission datasets; the other database is a special database generated by requests for selected criteria such as patients having specific diseases or undergoing specific procedures or medications. By analyzing the National Health Insurance Research Database (NHIRD), a nationwide view of specific clinically significant problems can be scrutinized.

For patients with elevated prostate specific antigen (PSA) levels or suspected lesion detected by digital rectal examination, transrectal ultrasound-guided (TRUS) prostate biopsy is the standard procedure for the diagnosis of prostate cancer. The incidence and prevalence rate of prostatic disease has increased because of the phenomenon of an aging population in Taiwan.[2] However, prostate cancer has a variable clinical course, and a significant proportion of prostate cancer cases may be indolent cancer. Thus, some patients with prostate cancer may die *with* it rather than die *of* it. There is also a study that demonstrates that extended biopsy improves the concordance of the Gleason scores between biopsy and prostatectomy, which indicates it has more complication risks.[3] Therefore, whether to check the PSA level in elderly men as a screening device for cancer has always been subject to debate, especially when considering complications associated with TRUS biopsy.[4–7] Our investigation aimed to study TRUS prostate biopsy and related complications in Taiwan, based on the claims of the NHI program.

2. Methods

From the NHIRD of Taiwan, we applied the data of all claims of patients who ever visited a urology clinic during the period of 2006–2010. In the resulting 5-year urology profile, we received all records from both admission (DO and DD files) and ambulatory clinics (OO and CD files). Codes for the ultrasound-guided procedure (19007B or 19002B) and the prostate puncture (29028C or 79401C) in combination were used to define TRUS biopsy.

Post-TRUS biopsy complications included voiding difficulty, significant bleeding, or infection requiring treatment. Postbiopsy voiding difficulty was indicated by an indwelling catheterization code after biopsy. Postbiopsy significant bleeding was defined as incidents necessary to be managed with endoscopic hemostatic procedures or transfusion. Infection that required treatment was defined by intravenous antibiotic administration for at least six dosages, and an admission period longer than 3 days, either during the admission of the biopsy or during the first admission within 7 days after biopsy.

The following risk factors were included: age, diagnosis of prostate cancer (heavy disease verification file, 185), hospitalization or nonhospitalization (i.e., biopsy performed either through admission or ambulatory clinics), and Charlson Comorbidity Index value[8] (CCI; values are 0, 1, 2, and ≥3).

Descriptive and comparative analyses were performed using SPSS version 17.0 software (SPSS Inc., Chicago, IL, USA). Relative risks were assessed by using Chi square or logistic regression tests in univariate analysis and multiple regression for multivariate analysis. This study was approved and certified by the Institutional Review Board (Taipei Veterans General Hospital, Taipei, Taiwan).

3. Results

In the 5-year urology profile, 12,968 TRUS biopsies were detected. The mean age of patients at the time of biopsy was 69.9 years (Fig. 1). Among the procedures, 6885 biopsies were performed during hospitalization and 6083 biopsies were performed at ambulatory clinics (Table 1); 4671 (36.02%) patients were diagnosed as having prostate cancer, which was confirmed by linkage to the heavy disease verification (HV) file. Thirty-two patients died within 30 days after biopsy (0.25% biopsy-related mortality); of these, 17 patients had an infection that required treatment (i.e., 0.13% biopsy-related sepsis-induced mortality).

Among the 12,968 TRUS prostate biopsies, 1266 (9.76%) patients had postbiopsy voiding difficulty (Table 2), which required the use of am indwelling Foley catheter. One hundred and forty-eight (1.14%) patients who underwent transfusion or endoscopic management also had significant bleeding (Table 3). Eight hundred and fifty-five (6.59%) patients who

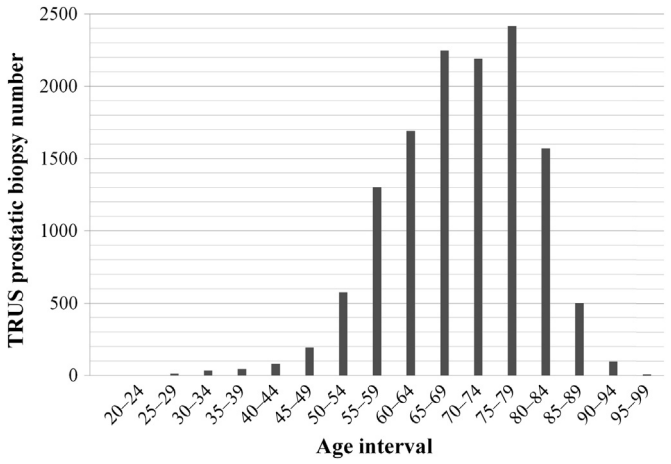

Fig. 1. Age distribution of the patients (representing 12,968 prostatic biopsies). The mean age is 69.9 years. TRUS = transrectal ultrasound-guided.

Table 1
Clinical data for all 12,968 prostatic biopsies, based on genitourinary service.

Admission (n = 6885)		Ambulatory visit (n = 6083)	
GU (n = 6457)	Not GU (n = 455)	GU (n = 6081)	Not GU (n = 2)
Malignancy diagnosis			36.0
Postbiopsy 30-d mortality			0.25
Biopsy-related sepsis-induced mortality			0.13

All data are presented as %.
GU = genitourinary department application.