Finasteride Use and Risk of Male Breast Cancer: A Case-Control Study Using Individual-Level Registry Data from Denmark, Finland, and Sweden

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Abstract

Background: In case reports, concerns have been raised as to whether finasteride use increases the risk of male breast cancer. Previous epidemiologic evidence on the potential link is conflicting. This study aimed to assess whether an association between finasteride use and male breast cancer exists after accounting for potential confounders.

Methods: The source population consisted of all men (≥35 years) from Denmark (1995–2014), Finland (1997–2013), and Sweden (2005–2014). Cases with incident male breast cancer were identified in the cancer registries and matched with 50 density-sampled, age, and country-matched male population controls per case. Exposure information on finasteride use was derived from the prescription registries. Potential confounders were identified using the directed acyclic graph methodology and measured by use of information from nation-wide registries.

Results: The study population comprised 1,005 male breast cancer cases and 43,058 controls. Confounder-adjusted odds of finasteride exposure were not statistically significantly increased [OR, 1.09; 95% confidence interval (CI), 0.77–1.54] in breast cancer cases relative to controls. There was no evidence of a dose–response relationship, as the group with greatest exposure to finasteride was associated with lowest OR of male breast cancer [OR, 0.72 (95% CI, 0.40–1.30)]. Sensitivity analyses did not reveal marked changes in results with different exposure definitions or for specific subgroups.

Conclusions: Results from this study provided no evidence that finasteride use was associated with male breast cancer.

Impact: This large confounder-adjusted study supports the view that exposure to finasteride is not associated materially with male breast cancer risk.

Introduction

Finasteride is a type II 5-alpha-reductase inhibitor (5-ARI) blocking the conversion of testosterone to the more potent androgen dihydrotestosterone. Dihydrotestosterone is the primary androgen of the prostate and hair follicles contributing to the development of benign prostatic hyperplasia (BPH) and androgenetic alopecia (1). Finasteride was approved in the dose of 5 mg for treatment of symptomatic BPH in 1992 and in the 1 mg dose for treatment of androgenetic alopecia in 1997 by the FDA (2, 3). Finasteride 5 mg was approved in March 1993 in Denmark, June 1992 in Finland, and September 1992 in Sweden. Finasteride 1 mg was approved in November 1998 in Denmark and Finland and April 1998 in Sweden. BPH can cause lower urinary tract symptoms (LUTS) when the enlarged prostate compresses the urethra (4). BPH is a common condition increasing with age with approximately 50% of men having BPH at age 50 and more than 80% having BPH at age 80 or older (5). Androgenetic alopecia or male pattern hair loss is a condition influenced by a combination of hereditary and hormone factors (6). The condition becomes a medical issue if causing distress and affecting quality of life (7).

Male breast cancer is a rare disease accounting for 0.6% of all breast cancers (8). The disease has an incidence rate from 1995 to 2014 of 0.5 case per 100,000 person-years in the Nordic countries (age-standardized to the World Standard Population; ref. 9). Case reports have raised concerns about a potential link between finasteride use and the development of male breast cancer. In 2009, the Medicines and Healthcare Regulatory Agency summarized in a review that 50 cases of male breast cancer have been reported worldwide in association with finasteride 5 mg and three cases in association with finasteride 1 mg (10). In the following years, epidemiologic studies have investigated the potential association between finasteride and male breast cancer; however, results from these studies have been affected by small or selected samples, inadequate confounder adjustment, and have shown conflicting results (11–15).

The rareness of male breast cancer disease makes it difficult to study and requires large study populations to obtain sufficient statistical power. None of the previous studies from the United States, United Kingdom, and Sweden found evidence for an increased risk of male breast cancer among finasteride users or

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Note: Supplementary data for this article are available at Cancer Epidemiology, Biomarkers & Prevention Online (http://cebp.aacrjournals.org/).

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users of any 5-ARI (i.e., finasteride or dutasteride) compared with nonusers (11–13, 15). The largest study to date, a cross-national Nordic cohort study (14), was based on approximately the same registry data as the current study, but with a shorter study period, different exclusion criteria, and only adjusting for calendar year, country, and age. This study found an increased incidence rate ratio for male breast cancer comparing finasteride users to nonusers of 1.44 [95% confidence interval (95% CI) = 1.11–1.88; ref. 14]. The authors stress that the reported higher incidence might be influenced by unmeasured confounding or surveillance bias, that is, finasteride users being more closely followed by physicians than nonusers, increasing their likelihood for having a breast cancer detected and diagnosed.

The Nordic countries have a long history of establishing and maintaining population registries including registries on cancer, hospital contacts, prescription redemption, and sociodemographic characteristics of the entire population (16–19). These data make it feasible to examine the association between finasteride and male breast cancer accounting for potential confounders by pooling data at the individual level from more than one country. This study aims to evaluate whether finasteride increases the risk of male breast cancer after accounting for potential confounding factors using cross-national registry data from Denmark, Finland, and Sweden.

Materials and Methods

Data sources
Individual-level data from Denmark, Finland, and Sweden were collected from nationwide registries by a national coordinator and transferred to Statistics Denmark, where a common database with individual-level records was established. Data were collected from the cancer registries, prescription registries, national patient registries covering all contacts with the hospital (outpatient and inpatient), civil registration systems, and social registries. Individual-level linkage between registries was possible due to the unique personal identity code assigned to all residents at birth or immigration (16, 18, 20). Data were collected for the period in each country where information from all registries was available. The study period was therefore 1 January 1995 to 31 December 2014 for Denmark, 1 January 1997 to 31 December 2013 in Finland, and 1 July 2005 to December 2014 in Sweden, respectively.

Study design
This study is being performed as a postauthorization safety study commitment to the European Union health authorities. A case–control design was used comparing finasteride redemptions among male breast cancer cases aged 35 years or older with a random sample of age and country-matched controls.

Cases
Male breast cancer cases were identified in the three cancer registries as men with first-ever breast cancer. However, male breast cancer patients with previous nonmelanoma skin cancer were included. Breast cancer cases were identified by the International Classification of Disease seventh revision (ICD-7) code 170 or ICD-O-3 code C50. The cancer registries in the Nordic countries are harmonized and characterized by high validity of diagnoses (17). Cases with previous radical prostatectomy (i.e., treatment for prostate cancer) were excluded to manage the unlikely situation that some of the prostate cancers were missing in the cancer registries. A new users design was applied by excluding cases with finasteride or dutasteride prescription redemptions in the first 6 month of registration in the prescription registries (21).

Controls
Density-sampling was used to sample 50 control men per case alive on the date as the respective male breast cancer diagnosis (index date). In Finland, controls were in addition matched by municipality of residence. Less than 50 controls were sampled for cases where fewer controls were eligible for sampling (especially among the oldest cases). Controls with cancer diagnosed before the index date, except for nonmelanoma skin cancer, were excluded. Same exclusion criteria were performed for controls as for cases, that is, previous radical prostatectomy and use of a new user design.

Exposure
Information on finasteride use was obtained from the prescription registries by use of the Anatomic Therapeutic Chemical (ATC) code 04CB01 (finasteride 5 mg) and D11AX10 (finasteride 1 mg). All drug purchases of prescription drugs are registered at the individual-level with information on date of purchase, ATC code, number of packages, and number of pills per package. Cumulative finasteride use was calculated by converting all finasteride prescription redemptions into 5 mg packs of 98 pills. In Finland, however, only reimbursed drugs are included in the registry meaning that information on drug purchases of nonreimbursed finasteride 1 mg was unavailable for the Finnish population (16). In addition, finasteride 5 mg was coded by ATC code 04CB04 in Finland from 1994 to 1996 and was not included in the prescription registry. Consequently, Finland was included in the study from 1997 onwards. In the main analysis, the exposed group was defined as men with at least two prescription redemptions of finasteride compared with unexposed men with none or only one finasteride prescription redemption.

Confounder selection and definition
Potential confounders for the association between finasteride use and male breast cancer were identified at an expert meeting and in the literature (22, 23). The directed acyclic graph (DAG) method was used to select the minimum set of potential confounders to adjust for and thereby minimize bias when estimating the effect of finasteride on male breast cancer (see the DAG in appendix Fig. S1; ref. 24). The potential confounders in the adjustment set were: age at the index date, country, benign prostatic hyperplasia, exogenous testosterone, estrogen therapy, Klinefelter syndrome, educational level, testicular disorders, and urbanization. Klinefelter syndrome and testicular disorder were defined as one or more diagnoses registered in the national patient registries before the index date and BPH as any diagnosis or BPH surgery registered before the index date. Estrogen therapy and exogenous testosterone were defined as having at least two prescription redemptions of the drugs before the index date. Educational level and urbanization were defined as the highest educational achievement (elementary: <9 years, short: 10–12 years, medium/long: >12 years) and living in an urban area, respectively. In Denmark and Sweden, information on educational level and urbanization was derived for the year before the index date and if this information was missing then the same year as the index date. In Finland, information on urbanization was obtained in the
same way, but information on educational level came from the latest available census (1995, 2000, 2005, or 2010). The ATC and ICD coding of all variables derived from the registries is presented in Supplementary Material Table S1.

Statistical analysis

The confounder-adjusted analysis of the association between finasteride and male breast cancer was performed by use of a conditional logistic regression model. Men with dutasteride use before the index date were excluded from the analyses, as dutasteride is a drug with same indication as finasteride and the purpose of the study was to examine the effect of finasteride exclusively (except for the sensitivity analysis including dutasteride users). It is unclear whether finasteride should be considered a drug that contributes to the development of cancer in the first initial phase or a cancer promoter that influences the late critical period in the carcinogenesis. Consequently, a lag period between finasteride use and diagnosis of cancer was not applied in the main analysis.

In addition to the main analysis, sensitivity analyses were performed to examine the robustness of the results when changing the exposure definition or restricting the study population. The sensitivity analyses included defining finasteride by cumulative use based on number of packages purchased (2–3 packs, 4–6 packs, or 7+ packs of 98 pills finasteride 5 mg versus less than two packs of finasteride); including only prescription redemptions of finasteride 5 mg; including persons who have only redeemed finasteride once in the exposed group; and grouping finasteride use into 0, 1, and 2 or more prescription redemptions. Moreover, the subgroups sensitivity analyses included adding persons with previous dutasteride use and combining exposure of finasteride and dutasteride altogether; restricting the study population to age of 65 years and above; only including Denmark and Finland (countries with longest follow up); requiring a 2-year lag period between finasteride use and cancer diagnosis; analyzing data without applying a new user design (i.e., including data on finasteride use in the first 6 months of registration); and stratifying the analysis by surveillance factors (persons with number of prescription redemptions and hospital contact below and above the mean as well as stratifying by cancer stage).

Finally, a random effect meta-analysis summarizing the evidence from four previous studies examining finasteride/5-ARIs and male breast cancer (11–15) together with this study was performed by use of Review Manager software version 5.3 (25). The meta-analysis was not initially included in the study protocol, but performed ad hoc to summarize the existing evidence on the association between finasteride and male breast cancer including results from this study. Studies included in the meta-analysis did include finasteride as the exposure (alone or together with dutasteride) and had male breast cancer as the outcome. The studies may differ in the study design, definition of the study population, and the exposure assessment. The study by Meijer and colleagues (2018; ref. 14) was not included in the meta-analysis because it was based on data with overlapping time period and study population as to the current study. The DAG was developed by use of DAGitty software version 2.3 (26). The remaining data management and analyses were performed by use of SAS software version 9.4.

Ethical considerations

According to the law in Denmark, Finland, and Sweden, registry-based studies can be performed without consent from the subjects if the data processing takes place with the only purpose of performing statistical or scientific studies of significant public health concerns and where the processing is required to perform these studies. Before data collection, data management, and data analyses, approval was obtained from the relevant national data agencies required in the three countries.

Results

In total 445, 255, and 328 incident male breast cancer cases were identified in Denmark, Finland, and Sweden and were matched with 22,233, 11,552, and 15,864 controls, respectively (Fig. 1). Controls with cancer before the index date (4,843), controls and cases with previous radical prostatectomy (1 case; 43 controls), or finasteride prescription redemptions in the first 6 months of registration (18 cases; 1,214 controls) were excluded.

Cases and controls with previous dutasteride use were excluded from the main analyses (4 cases; 491 controls) leaving 44,063 men for the analysis (1,005 cases; 43,058 controls).

Among male breast cancer cases, 38 (3.8%) were new users of finasteride before the index date compared with 1,258 (2.9%) of controls (Table 1). The distribution of confounding factors was similar for cases and controls, except for a slightly higher proportion of the cases with BPH relative to controls (13.2% of cases vs. 10.0% of controls).

The OR with corresponding 95% confidence interval (95% CI) of finasteride use was 1.18 (0.84–1.65) in the crude analysis accounting for age, country of residence, and calendar time (Table 2). The OR (95% CI) for men for the analysis (1,005 cases; 43,058 controls). The OR of exposure to finasteride before the index date compared with 1,258 (2.9%) of controls (Table 1). The distribution of confounding factors was similar for cases and controls, except for a slightly higher proportion of the cases with BPH relative to controls (13.2% of cases vs. 10.0% of controls).

The OR for the association between finasteride and male breast cancer was found when examining the cumulative finasteride use. Men who had redeemed 4–6 packs of 98.5 mg finasteride pills had the highest odds of male breast cancer compared with nonusers [1.24 (0.58–2.66)]. The OR for the association between finasteride and male breast cancer did not change markedly in analyses that included only 5 mg finasteride [1.09 (0.77–1.54)] or when including persons with only one prescription redemption in the exposed group [1.21 (0.89–1.64)]. In the analysis comparing the groups of users with one and two or more finasteride prescription redemptions with those who did not use finasteride, the group of men with only one prescription redemption had the highest OR [1.64 (0.93–2.89)].

Combining finasteride and dutasteride use [0.95 (0.68–1.32)], restricting the analyses to men aged 65 or above [1.02 (0.70–1.48)], inferring a 2-year lag period [0.88 (0.56–1.37)], including only those data from Denmark and Finland with the longest follow-up period [1.20 (0.81–1.78)], or not applying a new user design [1.15 (0.86–1.55)] did not change the results materially (Table 3).

The OR of exposure to finasteride was similar when restricting the analysis to men with frequent contact to the healthcare system (i.e., men with number of hospital contact and prescription redemptions above the mean [0.94 (0.63–1.41) and 1.03 (0.71–1.51), respectively]. Likewise, the ORs did not vary markedly between breast cancers of localized versus nonlocalized stage (Table 3).

The meta-analysis included the four previous studies examining finasteride/5-ARIs and male breast cancer (11–15) together...
with this study. The meta-analysis showed no evidence of heterogeneity ($P = 0.48$) among the five studies included (Fig. 2). The pooled relative risk estimate (95% CI) for the association between finasteride/5-ARI and male breast cancer was 1.00 (0.78–1.27).

**Discussion**

No significantly increased odds of exposure to finasteride were found for male breast cancer cases relative to controls. The OR for the association between finasteride use and male breast cancer decreased when accounting for potential confounders. In the protocol of this study, confounding was assumed to be an important bias of the association between finasteride and male breast cancer; however, the actual results did not support that confounding did influence the results markedly although the estimates attenuated slightly. Changes in the definition of finasteride use or performing restrictions of the study population did not change the results materially. No increased OR for the association between finasteride and male breast cancer was seen among men who were often in contact with the healthcare system and therefore more likely to undergo disease surveillance.

Results from this study contribute to the existing epidemiologic evidence on the association between finasteride and male breast cancer in supporting no evidence for a raised risk, and if there is any raised risk it is likely to be small or modest. The first epidemiologic study from the United States found no evidence of an association between 5-ARIs and male breast cancer with an OR (95% CI) of exposure in one or more years of 0.70 (0.34–1.45 ref. 11). Likewise, Duijnhoven and colleagues (2014) found no evidence that men treated with 5-ARIs had an increased risk of...
male breast cancer with an OR (95% CI) of 1.08 (0.62–1.87). In addition, no association between 5-ARI and male breast cancer was observed in two smaller studies from United Kingdom and Sweden, respectively (13, 15). A cross-national study by Meijer and colleagues (2018) was based on data from the Nordic countries in line with this study and found a statistically significant increased incidence rate of male breast cancer among finasteride users compared with nonusers [IRR (95% CI) = 1.44 (1.11–1.88); ref. 14]. Some differences in study population and design exist between these two Nordic studies, which explain the lower risk estimate found in this study relative to the previous Nordic study (i.e., different follow-up period, exclusion criteria, confounder adjustment, exposure definition, and Norway included in the earlier study). When analyzing data from this study to mirror the analysis of Meijer and colleagues (2018) with a shorter study period, no exclusion criteria and including men with only one prescription redemption of finasteride in the exposed group, the estimate of the association between finasteride and male breast cancer was 1.60 (1.18–2.17). It was not possible to study the effect of including Norway as Norwegian data were not available in this study. However, as only one male breast cancer case from Norway was exposed to finasteride in the Meijer and colleagues (2018) study, we do not expect the difference between the two studies to be explained by the exclusion of Norwegian data. This study is likely to provide a more valid estimate of the association between finasteride use and male breast cancer than Meijer and colleagues (2018) as a more advanced study design was applied incorporating a new user design, including longer follow-up period (important if the latency period is long) and not including men with only one prescription redemption as exposed as these men are likely not to have consumed the drug or only used it for a very short time.

The study was performed as a response to a drug safety concern regarding a potential signal of increased risk of male breast cancer, a serious but rare disease, meaning that the width of the confidence interval is important to consider. However, given the low age-adjusted incidence rate of breast cancer among men in the Nordic countries from 1995 to 2014 of about 0.5 cases per 100,000 person years (9), even an OR or RR close to the upper limit of the 95% confidence interval (i.e., 1.54 in this study and 1.27 in the pooled meta-analysis) results in a small absolute number of male breast cancer cases attributable to finasteride.

Strengths of the study include the advantage of merging nationwide individual-level data across countries providing a source population of the entire male population aged 35 years or older from three countries. Hence, the study population was representative of adult men in the Nordic countries increasing the generalizability of the results to other populations outside the Nordic countries especially other populations mainly consisting of Caucasian men. Moreover, a merit was the large number of men exposed to finasteride. A previous study reported a period prevalence of finasteride use among men aged 15 years and older to range from 4.9 users/1,000 men in Denmark to 18.2 users/1,000 men in Finland (27). Because of the long history of the population registries in the Nordic countries, another merit of this study was the long follow-up of finasteride users making it possible to study a rare disease with potentially long latency period as is the case with male breast cancer. Another strength of the study is that the prescription registers cover close to all prescription drugs except for drugs handled out in the hospitals and online drugs purchased.
from other countries. In Denmark, more than 99% of finasteride is purchased at pharmacies outside the hospitals and this proportion is assumed to be similar in Finland and Sweden (28). No subsidies are given for prescription drugs purchased via the internet from other countries and it is therefore unlikely to be used often for subsidized drugs as there is no economic benefit for the purchaser. Finally, the high validity of cancer diagnoses in the Nordic cancer registries and the harmonization of the cancer and prescription registries of the Nordic countries contribute to high internal validity of the results (17, 19, 29).

A limitation of the study is the unknown drug compliance, as finasteride exposure is based on dispensed and not necessarily consumed drugs. However, this potential overestimation of the exposure was compensated by including only persons with at least two prescription redemptions in the exposed group increasing the likelihood that the drug was actually consumed. It was not feasible to adjust for the potential confounders Klinefelter syndrome and estrogen therapy, as too few men had the diagnosis or had received the treatment. As an alternative strategy, a restriction of the analysis was performed by excluding men with Klinefelter syndrome or estrogen therapy (n = 14, only controls) and this did not change the results. Even though this study is the largest to date with 1,005 cases, a limitation of the study is that only 38 cases were exposed to finasteride.

In conclusion, no evidence of an association between finasteride and male breast cancer was found in this large and

Table 3. Sensitivity analyses with restriction, stratification, alternative definition of the study population, and surveillance factors

<table>
<thead>
<tr>
<th>Cases</th>
<th>Controls</th>
<th>Crude OR (95% CI)</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonuser</td>
<td>967</td>
<td>41,945</td>
<td>1.00 (ref)</td>
</tr>
<tr>
<td>User</td>
<td>42</td>
<td>1,604</td>
<td>1.02 (0.74–1.41)</td>
</tr>
<tr>
<td>Only persons ≥65 years</td>
<td>Nonuser</td>
<td>575</td>
<td>23,260</td>
</tr>
<tr>
<td>User</td>
<td>33</td>
<td>1,322</td>
<td>1.12 (0.78–1.61)</td>
</tr>
<tr>
<td>With 2-year lag period</td>
<td>Nonuser</td>
<td>983</td>
<td>42,186</td>
</tr>
<tr>
<td>User</td>
<td>22</td>
<td>872</td>
<td>0.96 (0.62–1.49)</td>
</tr>
<tr>
<td>Only Denmark and Finland</td>
<td>Nonuser</td>
<td>650</td>
<td>28,812</td>
</tr>
<tr>
<td>User</td>
<td>30</td>
<td>934</td>
<td>1.30 (0.89–1.91)</td>
</tr>
<tr>
<td>Including finasteride use in the first 6 months of registration</td>
<td>Nonuser</td>
<td>970</td>
<td>42,512</td>
</tr>
<tr>
<td>User</td>
<td>53</td>
<td>1,705</td>
<td>1.23 (0.92–1.65)</td>
</tr>
</tbody>
</table>

Surveillance factors

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Cases</th>
<th>Controls</th>
<th>Crude OR (95% CI)</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonuser</td>
<td>415</td>
<td>23,274</td>
<td>1.00 (ref)</td>
<td>1.00 (ref)</td>
</tr>
<tr>
<td>User</td>
<td>10</td>
<td>332</td>
<td>1.64 (0.84–3.19)</td>
<td>1.64 (0.84–3.23)</td>
</tr>
<tr>
<td>Prescription redemptions</td>
<td>Nonuser</td>
<td>469</td>
<td>21,330</td>
<td>1.00 (ref)</td>
</tr>
<tr>
<td>User</td>
<td>6</td>
<td>161</td>
<td>1.76 (0.75–4.15)</td>
<td>1.78 (0.74–4.25)</td>
</tr>
<tr>
<td>Cancer stagec</td>
<td>Nonuser</td>
<td>437</td>
<td>18,856</td>
<td>1.00 (ref)</td>
</tr>
<tr>
<td>User</td>
<td>19</td>
<td>572</td>
<td>1.30 (0.81–2.10)</td>
<td>1.13 (0.69–1.84)</td>
</tr>
</tbody>
</table>

c104 cases (10.4%) had no information on cancer stage and were therefore excluded from this analysis as were their corresponding 4,430 controls.

Figure 2.

Meta-analysis of the studies on finasteride/5-ARI and male breast cancer, including four previous studies and this study. The individual studies included in the meta-analysis are illustrated by squares, with the size of the square symbolizing the size of the study, and the 95% confidence intervals (CI) are illustrated by the width of the line. The pooled estimate is shown by a black diamond, with the width of the diamond illustrating the 95% CI.

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confounder-adjusted cross-national registry-based study with a long follow-up period.

Disclosure of Potential Conflicts of Interest
A. Green and M. Emneus served as consultants for Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., in connection with the study presented in this paper. No potential conflicts were disclosed by the other authors.

Authors’ Contributions
Conception and design: T.M. Kjærulff, A.K. Ersbøll, A. Green, M. Emneus, K. Brasso, P. Iversen, E. Pukkala, L.C. Thygesen
Development of methodology: T.M. Kjærulff, A. Green, K. Brasso, P. Iversen, E. Pukkala, L.C. Thygesen
Acquisition of data (provided animals, acquired and managed patients, provided facilities, etc.): T.M. Kjærulff, A. Green, M. Emneus, K. Brasso, E. Pukkala, K. Bolin, L.C. Thygesen
Analysis and interpretation of data (e.g., statistical analysis, biostatistics, computational analysis): T.M. Kjærulff, A.K. Ersbøll, A. Green, K. Brasso, P. Iversen, E. Pukkala, K. Bolin, L.C. Thygesen
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