

Research Status of Androgen Deprivation Therapy Monotherapy and Combination Therapy for Prostate Cancer: A Scoping Review

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Background: Prostate cancer (PC) is a common malignant tumor. Although androgen deprivation therapy (ADT) drugs are widely used in the treatment of PC, to date, clinical research on ADT drugs has not provided a clear overview of the existing treatment regimens. The purpose of this study is to use scoring review to sort out relevant research, present relevant research evidence, and identify recommended guidance for selecting therapeutic strategies.

Methods: PubMed, Embase and Cochrane Library databases were searched for literature published until September 2025. Statistical analysis was conducted on the main characteristics of the included studies, with a primary focus on changes in the medication regimens of the four ADT drugs identified in clinical studies.

Results: Ultimately, 160 literatures with 126 randomized controlled trials (RCTs) were included in the analysis. There were 52, 67, ten, and 16 studies evaluating leuporelin, goserelin, triptorelin, and degarelix, respectively. The main medication regimens for ADT drugs included monotherapy and combination therapy with first generation anti-androgen drugs, novel hormonal drugs, and other treatments. In RCTs that evaluated leuporelin and goserelin, numerous studies involved all four medication regimens. However, due to the relatively late regulatory approval of triptorelin and degarelix, these were mainly studied as monotherapy. There were only six studies from China.

Conclusion: Although numerous studies have evaluated the efficacy of ADT drugs for the treatment of PC, there is still a paucity of high-quality research across multiple domains. Furthermore, there is a relative lack of in-depth research involving Chinese patients.

Keywords: ADT drugs, monotherapy, combination therapy, prostate cancer, scoping review

Introduction

More than 1,467,854 new cases of prostate cancer (PC) were reported worldwide in 2022, with PC ranking fourth among all malignant tumors.¹ With population aging, the absolute incidence is expected to reach 2.9 million by 2040.² In China alone, 134,200 new cases of PC were reported in 2022, making PC ninth among all malignant tumors.³ Longitudinal modelling by Feng et al further indicates that, although the global age-standardized incidence rate (ASR) of PC is expected to decelerate, China will experience a pronounced ASR increase between 2022 and 2046, reflecting a disproportionate rise in both case numbers and population-level burden.⁴ The treatment options for PC are diverse and include surgery, drug therapy, radiotherapy, and ablation.^{5,6} Commonly used drugs for PC include androgen-deprivation therapy (ADT), as well as anti-androgen, taxane chemotherapy, and immune-related drugs, most of which are often used in combination with ADT or as part of a treatment strategy involving ADT.⁷ Enzalutamide, either alone or in combination with gonadotropin-releasing hormone (GnRH) analog, was approved by the FDA in 2023 for non-metastatic castration-sensitive patients with PC who had evidence of biochemical recurrence and were at high risk of metastasis. Enzalutamide is the only drug approved for single-agent use in this population.⁸ ADT, also referred to as hormone therapy, is commonly used for the treatment of advanced metastatic PC.⁹ The treatment recommendations presented in guidelines mainly refer to the ADT category of GnRH agonists and antagonists, rather than to specific drugs. Furthermore, the current status of research addressing issues such as differences in clinical focus and recent changes in

treatment regimens of specific ADT drugs remains unclear. We conducted a scoping review to summarize relevant studies with the aims of presenting the current state of research on specific ADT drugs and their combination therapies, highlighting changes in treatment regimens, identifying clinical focus areas, and providing guidance for optimizing ADT regimens for the treatment of PC.

Materials and Methods

Eligible Criteria

Randomized controlled trials (RCTs) that enrolled adult patients with PC who were treated with the ADT drugs leuporelin, goserelin, triptorelin, and degarelix were included. To be eligible for inclusion, studies were required to report data on these four drugs of individually, with no restrictions on the control drugs.

Literature Search

Following the PRISMA-ScR guidelines,¹⁰ databases of PubMed, Embase and Cochrane library, were searched for relevant studies published up to September 2025. The included studies were restricted to English-language publications. The search strategies for each database are shown in [Supplementary File 1](#).

Literature Screening

One investigator screened the literature for inclusion, and another investigator checked the results. Studies identified for potential inclusion were screened again using the full text. If there were inconsistencies between the inclusion and exclusion of certain studies, the final decision was made after discussion between the two investigators, and if necessary, with input from a third party. Attempts were made to contact the author directly to clarify any uncertainties and to inquire about relevant details to better determine whether a study should be included.

Data Extraction and Integration

Data were extracted using a predefined spreadsheet. Data extraction was performed by two investigators. Any disagreements were resolved by a third reviewer. Information extracted included: general study characteristics (year of publication); population (diagnosis, age, and total number of participants); method (research design, population allocation method, and blinding setting); intervention and control measures (medication type and frequency, dosage and administration route).

Data Expression and Statistical Analysis

This descriptive study primarily quantified the number of RCTs and analyzed their temporal trends in relation to the four ADT drugs. The findings were graphically presented through multiple visualization methods, including line graphs (for temporal trends), bar graphs (for categorical comparisons), and bubble charts (for multivariate data representation).

Results

General Information

The preliminary search identified 3,792 relevant studies. We excluded the following: 1,249 duplicate studies, 1,992 studies deemed irrelevant among title and abstract screen, 134 studies whose original text could not be obtained, a total of 257 studies were excluded among full text screening, including 50 studies with unreasonable interventions, 28 studies without reported outcomes, 38 studies with unreasonable designs, 126 abstracts, 12 studies of dosage/dose comparison of the same medicine, and three non-English language studies. Finally, 160 literatures involving 126 RCTs were included in the analysis ([Figure 1](#)). Among these, were 52 RCTs investigating leuporelin with sample sizes of 21 to 1,071 cases that were published between 1984 and 2024, with follow-up periods of one month to 7.3 years; and 67 RCTs investigating goserelin with sample sizes of 21 to 1,521, published between 1987 and 2024, with follow-up periods of one month to 13 years. Approximately 65% of the RCTs evaluating leuporelin and goserelin were multicenter trials. The number of RCTs with a large sample size evaluating these two drugs was same, both with ten RCTs. One RCT on goserelin reported a sample size of $\geq 1,000$, and two RCTs on leuporelin. Ten RCTs evaluated triptorelin with sample sizes of 38 to 918 that

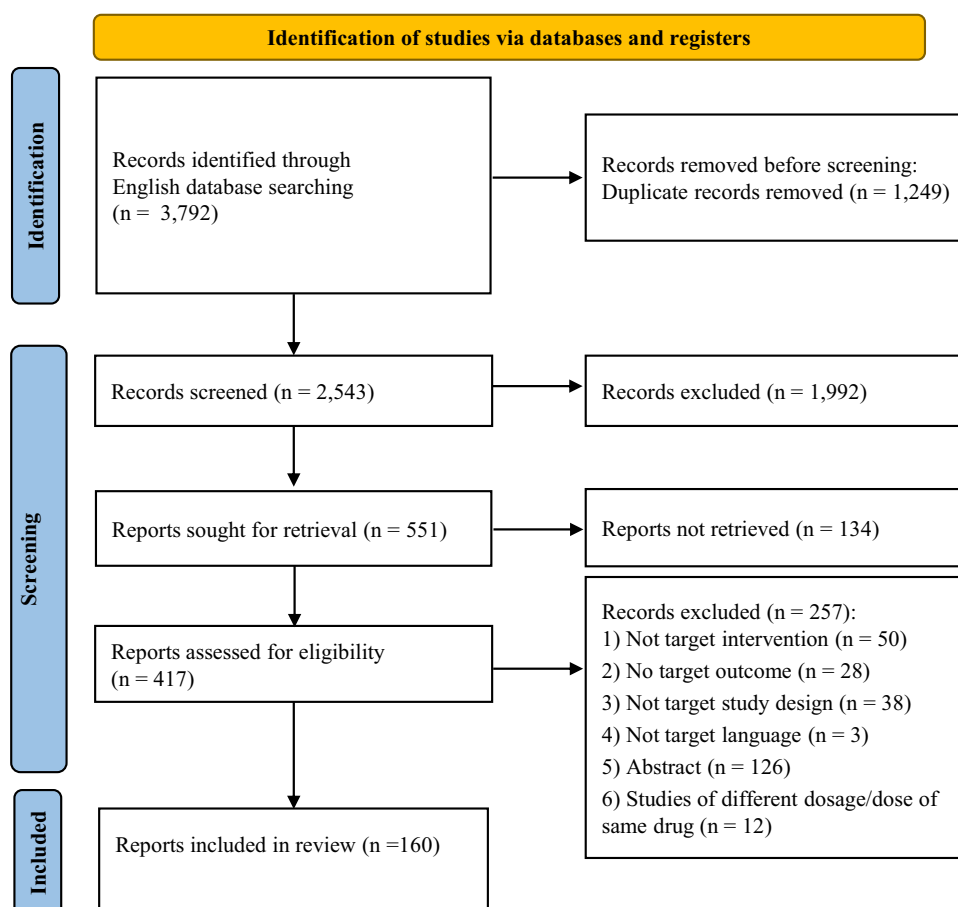


Figure 1 PRISMA flowchart of study selection.

were published between 1996 and 2025, with follow-up periods of one month to five years. Sixteen RCTs evaluated degarelix with sample sizes of 28 to 610 that were published between 2010 and 2024. Seventy-five percent of RCTs evaluating both triptorelin and degarelix were multicenter. Two triptorelin RCTs and one degarelix RCT reported sample sizes of ≥ 500 but ≤ 1000 . Overall, these studies covered all clinical stages of PC from early localized PC to advanced distant metastatic disease. However, a notable gap remains, as most studies have involved populations with mixed disease stages and lacked analyses dedicated to any single disease stage.

Changes in Treatment Regimen

The treatment regimens included in the study were classified according to the target drug (Figure 2). Of the 52 studies evaluating leuporelin, 27 compared leuporelin monotherapy with other drugs—namely estrone, chlorpromazine acetate, cyproterone acetate, relugolix, GTx-758, and abarelix. In addition, 18 studies analyzed the effect of leuporelin in combination with other treatments, and two studies compared the combination of leuporelin with surgery or radiotherapy with leuporelin alone or surgery alone. Park et al investigated the long-term oncological outcomes of a randomized trial comparing leuporelin combined with external beam radiation therapy (EBRT) and leuporelin alone in patients with locally advanced PC. This study reported the oncological benefit of combining EBRT with leuporelin in the treatment of locally advanced PC.¹¹

Among the 67 studies evaluating goserelin, 25 compared goserelin monotherapy with other drugs such as—diethylstilbestrol, bicalutamide, estramustine, and cyproterone acetate. A total of 21 studies evaluated goserelin combination therapy, and 12 compared goserelin treatment with surgery or radiotherapy. Among the ten studies evaluating triptorelin, three compared triptorelin with leuporelin, six compared combination therapy containing triptorelin

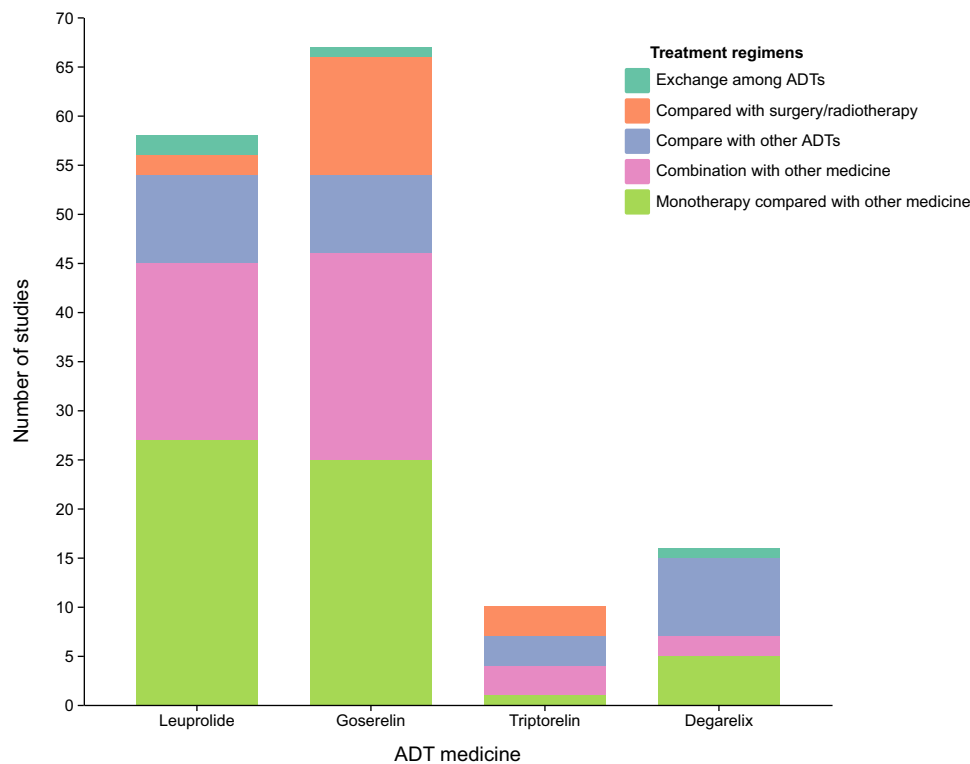


Figure 2 Study design of all included studies.

Abbreviation: ADT, androgen deprivation therapy.

(including three studies compared with surgery or radiotherapy), and another study compared with active surveillance. Of the 16 studies evaluating degarelix, five compared it with other drugs, eight studies compared it with leuporelin and goserelin, two studies compared combination therapy with other medicines, and one study focused on the exchange between degarelix and leuporelin.

We analyzed the temporal trend in the number of ADT-related RCTs (Figure 3). For leuporelin and goserelin, drugs that were developed and introduced earlier, numerous related RCTs studies conducted with continuous publication of research results. More studies evaluating goserelin were conducted between 1990 and 2000, with studies evaluating leuporelin appearing more frequently after 2000. The number of triptorelin-related studies was relatively small, and the timing of publications was more dispersed. Degarelix is the latest drug to be developed and introduced, although in recent years, degarelix-related research has been published almost every year. Thus, it can be seen that leuporelin and goserelin have been extensively studied in clinical practice. Leuporelin has been the most widely used a control drug in RCTs, while degarelix has received greater attention in recent years. Few triptorelin-related RCTs have been published since 2018.

Further analysis of the medication regimens used in various RCTs (Figure 4) revealed the existence of four regimens: ADT monotherapy, ADT combined with first generation anti-androgen drugs, ADT combined with novel hormonal drugs, and ADT combined with other treatments. In RCTs evaluating leuporelin and goserelin, all four types of medication regimens have been used in recent years. However, most studies on triptorelin or degarelix involved monotherapy, with few RCTs evaluating the combination of triptorelin or degarelix with first generation anti-androgen drugs or novel hormonal drugs. Notably, there is a lack of RCTs evaluating the combination of degarelix with other drugs, and the sample sizes of RCTs evaluating triptorelin and degarelix are relatively small.

According to the specific analysis of the four medication regimens, the monotherapy RCTs included 30 trials of leuporelin, 34 trials of goserelin, four trials of triptorelin, and 13 trials of degarelix. In the RCTs of ADT combined with first generation anti-androgen drugs, there were 14 trials of leuporelin, 29 trials of goserelin, one trial of triptorelin, and two degarelix-related trial. Regarding ADT combined with novel hormonal drugs, there were five trials of leuporelin, two trials of goserelin, three trials of degarelix, and no trials of triptorelin. Thus, leuporelin in combination with novel

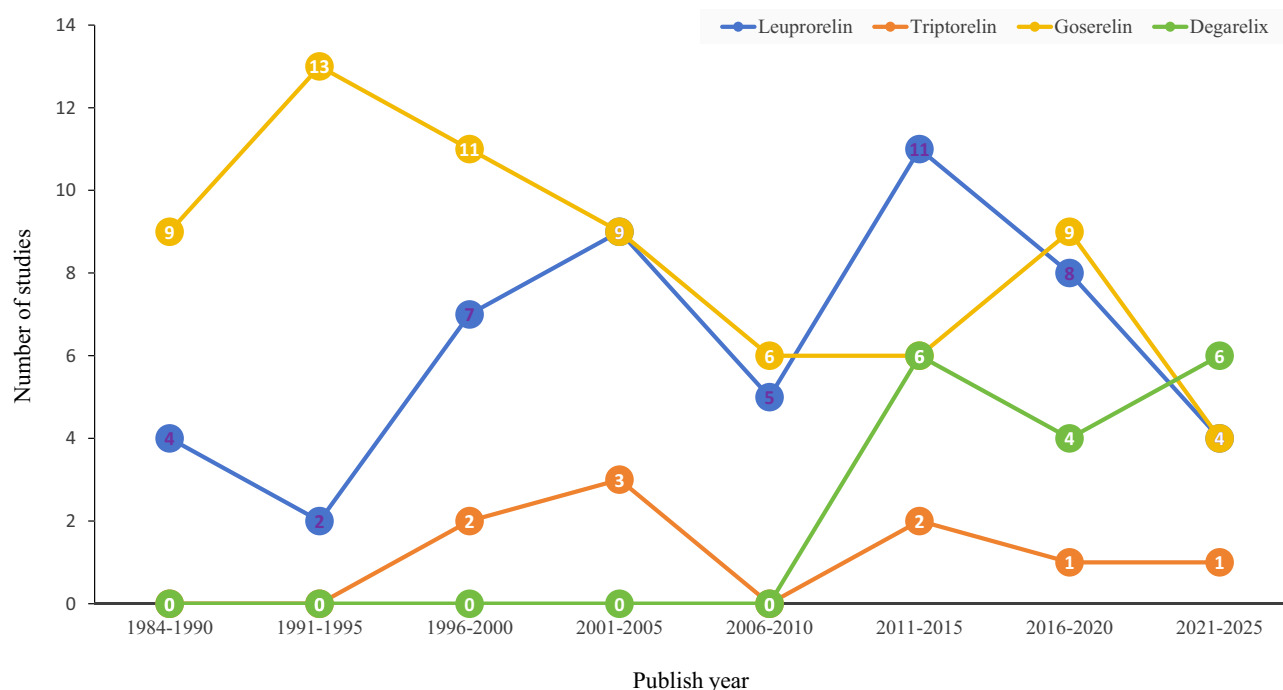


Figure 3 Publication status of studies of four androgen deprivation therapy drugs.

hormonal drugs has been the most frequently studied. In recent years, more trials of leuporelin and degarelix combination therapies with novel hormonal drugs have been conducted. There have been trials of ADT combined with other treatments, including 11 studies on leuporelin, ten studies on goserelin, three studies on triptorelin, and no study involving degarelix. There were nine studies on the combination of ADT and radiotherapy, with the drugs used in combination with beinguporelin or goserelin, mainly compared to radiotherapy alone. Testicular resection surgery was evaluated in nine studies. Except for one study that compared leuporelin combined with flutamide plus surgery with testicular resection surgery, all other studies evaluated goserelin. Four studies evaluated goserelin in combination with the androgen receptor blocker flutamide. From the perspective of time distribution (Figure 4), the four medication regimens of leuporelin and goserelin were relatively evenly distributed. Among the leuporelin-related studies, either monotherapy or leuporelin in combination regimens has been increasingly studied in recent years.

Discussion

This review analyzed studies that included RCTs related to four ADT drugs currently on the market and explored multiple dimensions, such as publication time, ADT medication regimen, and sample size of relevant clinical trials. Our results showed that there were more RCTs related to leuporelin and goserelin between 1984 and 2024. In recent years, the number of degarelix-related studies has significantly increased. On the clinical research registry website (clinicaltrials.gov), we retrieved 39, 27, 24, and 22 ongoing trials on leuporelin, goserelin, triptorelin, and degarelix, respectively. Both leuporelin and goserelin have been extensively evaluated in four different medication regimens, whereas research on triptorelin and degarelix has mainly focused on monotherapy. Regarding combination therapy, until recently, there have been more studies on ADT combined with first-generation anti-androgen drugs. In addition, the number of studies evaluating combined therapy with novel hormonal therapy or other drugs has significantly increased in recent years. Among novel hormonal therapy combination regimens, leuporelin has been the most studied. In recent years, leuporelin has been investigated more in clinical trials than other androgen ADT drugs, both as a monotherapy and in combination with other therapeutic agents. This trend can be attributed to the availability of leuporelin in multiple dosage formulations and its extensive use in clinical practice.¹²

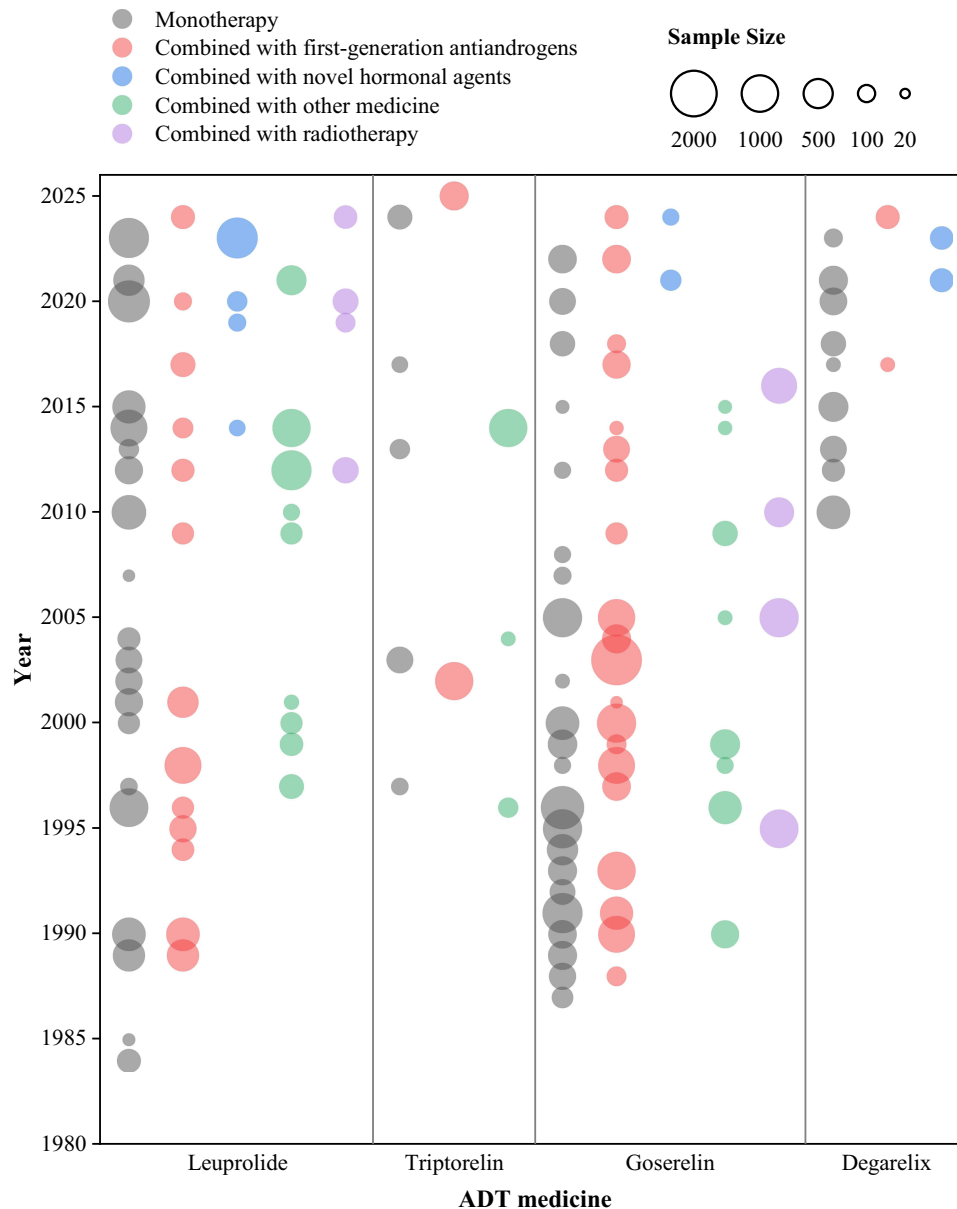


Figure 4 Treatment regimens of four androgen deprivation therapy drugs.

In the era of potent androgen receptor pathway inhibition, novel hormonal therapies—abiraterone, enzalutamide, apalutamide, darolutamide and the recently approved rezvilutamide—have shifted the ADT treatment regimen from sole androgen suppression to a next-generation combined androgen blockade. Several Phase III RCTs¹³ demonstrates that adding these next-generation drugs to ADT consistently prolongs overall survival and radiographic progression-free survival across the continuum of metastatic hormone-sensitive, non-metastatic castration-resistant, and first-line metastatic castration-resistant PC, while preserving quality of life. Consequently, contemporary ADT algorithms should no longer be restricted to gonadal suppression alone; instead, upfront combination therapy with a novel hormonal agent is now the evidence-based standard for all high-volume or rapidly progressive disease.

According to the results of this study, there have been relatively sufficient clinical studies on the monotherapy of four ADT drugs, especially leuprolide, goserelin, and degarelix, which have been evaluated in clinical practice for their efficacy and safety in the treatment of PC at all stages. A large amount of evidence suggests that ADT can be used as the initial and adjuvant treatment for moderate to high-risk localized PC, and as the first-line treatment for hormone-sensitive metastatic PC.^{7,14} ADT

remains one of the initial and adjuvant treatments for PC with limited regional lymph node metastasis and can be used alone or in combination with external radiation therapy.¹⁴ To improve the quality of life of men undergoing systemic treatments, ADT has been recommended in combination with aerobic and resistance exercise.¹⁴ Notably, ADT is not recommended for pathological nodal stage 0 (pN0) patients. In addition, ADT monotherapy should only be offered to patients who are unwilling or unable to receive any form of local treatment if they have a prostate-specific antigen (PSA)-doubling time < 12 months, a PSA > 50 ng/mL or a poorly-differentiated tumor.¹⁴

On the basis of monotherapy, numerous studies have evaluated combination therapy with leuporelin and goserelin. In more in recent years, combined treatment with first-generation anti-androgen drugs and as well as combined treatment with novel hormonal therapy have been increasingly investigated. In addition to combined treatment with novel hormonal drugs and first-generation anti-androgen drugs, the combination of these ADT drugs with radiotherapy or surgery has also been prescribed to improve PC treatment outcomes. ADT combination therapy is strongly recommended for the treatment of metastatic hormone sensitive prostate cancer (mHSPC),^{15–18} which can be combined with novel hormonal drugs such as abiraterone, enzalutamide, and apalutamide, and first-generation anti androgen drugs such as bicalutamide, and flutamide, as well as external radiation therapy, cryotherapy, surgery.¹⁸ Nonetheless, our analysis of existing ADT-related RCTs and the level of evidence presented in the guidelines suggest that there is currently a lack of sufficient horizontal comparative studies of ADT drugs to investigate whether there are significant differences in efficacy and safety among the four ADT drugs when monotherapy is used to treat PC or whether they are more suitable for specific populations. For these patients, additional rigorously designed clinical studies are needed to evaluate the efficacy and safety of intermittent ADT or ADT combined with flutamide. ADT may also be used in combination with bicalutamide, flutamide, or primary lesion surgical resection or brachytherapy for the treatment of metastatic hormone sensitive PC with a high tumor burden, although higher-level evidence is required.

This review also found that, among the included studies, there were only six studies from China, including one involving both Chinese and Russian.¹⁹ Of these, only two multicenter studies had sample sizes of 226 and 283 cases.^{19,20} The other four had single center sample sizes of 54,²¹ 100,²² 104,²³ and 54.²⁴ Although, when compared with European and American countries, the incidence of PC in China is relatively low, by 2022, the number of new cases of male PC in China was estimated to reach 134,200, with 47,500 deaths.³ From the perspective of the number of new cases, there may be some differences in the occurrence and development of PC between Chinese, European, and American men. Therefore, it is necessary to conduct in-depth clinical research on Chinese men with PC. However, there is currently relatively little research on the therapeutic efficacy, safety, and combination therapy of the four ADT drugs in Chinese patients. A significant limitation of the existing RCTs of ADTs is that most studies involve cohorts with mixed disease stages, which precludes stage-specific analysis. Furthermore, there is currently a lack of research comparing the response of Chinese patients to ADT with that of patients in Europe and America.

One strength of this review is the use of a systematic approach to research ADT drugs in the treatment of PC. A comprehensive search was performed, and through a rigorous screening process, the most relevant studies were included. In particular, this review focused on analyzing the results from RCTs to provide a clear overview of the current research landscape in the field and identify potential investigative directions for future studies. However, this study also has limitations. First, this review included only English-language literature and may have overlooked some high-quality RCTs published in other languages. Second, recent research findings may have been omitted as they have not yet been formally published.

Conclusion

Our findings highlight that, as the therapeutic landscape evolves, the clinically relevant differences among ADT options demand attention. And despite extensive ADT literature, robust prospective trials are urgently required to compare ADT-based regimens, particularly combined with novel hormonal therapies, across well-defined disease stages and ethnic populations, so as to refine individualized algorithms and guide evidence-based ADT selection.

Abbreviations

PC, prostate cancer; ADT, androgen deprivation therapy; RCTs, randomized controlled trials; ASR, age-standardized incidence rate; GnRH, gonadotropin-releasing hormone; EBRT, external beam radiation therapy; PSA, prostate-specific antigen; pN0, pathological nodal stage 0; PSA, prostate-specific antigen; mHSPC, metastatic hormone sensitive prostate cancer.

Data Sharing Statement

Original data generated and analyzed during this systematic review are included in this article.

Ethics Approval and Informed Consent

This scoping review of published literature did not require institutional ethics approval or informed consent.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Disclosure

The authors have no competing interests to declare.

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