

The Progesterone Receptor Antagonist Ulipristal Markedly Improved Quality of Life in a Patient with end-Stage Prostate Cancer

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Abstract:

Most cancers to metastasize require the activation of membrane progesterone receptors (mPRs) to produce immunomodulatory proteins, e.g., the progesterone-induced blocking factor (PIBF). The PR receptor antagonist mifepristone has been used to provide significant palliative benefits for very advanced cancers without any more treatment options. Unfortunately, because mifepristone gained notoriety as an abortifacient there are many barriers for prescribing this drug. Not all PR antagonists have the same mechanism of actions. Cell line studies show that mifepristone suppresses PIBF, but there are no such studies as yet showing that the PR antagonist ulipristal also suppresses PIBF. Nevertheless, the case presented here shows that ulipristal can provide marked palliative benefits for an 82-year-old male with end stage treatment resistant prostate cancer with metastatic lesions to bone, lungs, and brain. In fact, this is the first case report showing that any selective progesterone receptor modulator can treat end stage prostate cancer.

Key words: selective progesterone receptor modulator; advanced prostate cancer; progesterone induced blocking factor; ulipristal

Introduction

There is evidence that both the fetal semi-allograft and malignant tumors activate membrane progesterone receptors (mPRs) to produce immunomodulatory proteins e.g.; the progesterone induced blocking factor (PIBF) and the progesterone receptor membrane component-1 (PGRMC-1) protein [1-4]. There are multiple case reports of various types of very advanced cancers that have responded extremely well to the progesterone receptor antagonist/modulator mifepristone resulting in

significant extension of life and marked improvement of quality of life [5-8]. The mechanism of action for mifepristone seems to be by inhibiting the activation of mPRs resulting in suppression of immunomodulatory proteins e.g., PIBF and PGRMC-1, thus inhibiting further growth of metastatic lesions and even causing regression of many of these metastatic lesions [3,7,9]. (See Figure 1).

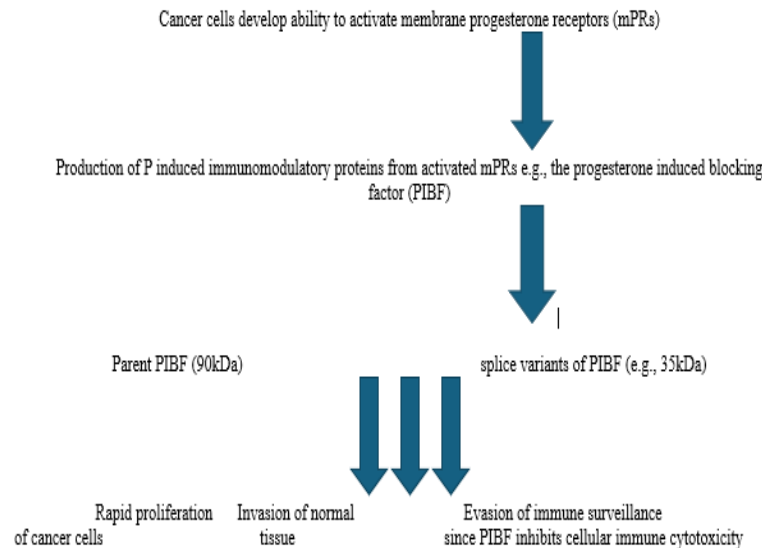


Figure 1: Hypothetical model of one factor allowing increased cancer aggressiveness

- PR antagonists/modulators inhibits PIBF production from mPRs allowing innate natural killer cells, macrophages, and cytotoxic t-cells to attack the cancer cells
- Other mPR induced immunomodulatory proteins e.g., progesterone receptor membrane component-1 may also be suppressed by PR antagonists.

A minority of cancers not only have mPRs (which may be present in all cancers), but also have nuclear P receptors (nPRs) present. These cancers may include some breast, ovarian, endometrial, and prostate cancers [10,11]. The thought was that possibly the nPR was important for the cancer to proliferate, and thus blocking the nPR by a PR antagonist could possibly help to thwart cancer spread. However, early studies using PR antagonists/modulators for nPR positive cancers were not that impressive [12-18]. The possible reason why mifepristone or other PR antagonists may not be as effective for cancers that are positive for the nPR, but yet very effective for cancers devoid of the nPR, is that the activation of the nPR may lead to the production of immunomodulatory factors that are protective [4,7,10,11,19]. Thus, the treatment with a PR antagonist...when the tumor is positive for the nPR may suppress factors made by the nPR that help prevent cancer spread while also suppressing immunomodulatory factors e.g., PIBF and PGRMC-1 that the tumor uses to promote cancer spread thus cancelling out each other [19]. Some research studies find that once tumors with a better prognosis initially related to the presence of the nPR, they will rapidly metastasize if the cancer loses the nPR. This is the better time to consider therapy with a PR antagonist/modulator, e.g., mifepristone [19]. Mifepristone as a single agent has been used by our group usually at 200mg per day orally (with a minority of cases at 300mg/ day) to treat a variety of patients with very end stage cancers not known to be associated with the nPR. Thus, the PR antagonist was directed against mPRs and their production of immunomodulatory proteins [3,6]. These cancers have included breast cancer, transitional cell carcinoma of the renal pelvis, leiomyosarcoma, thymic epithelial cell cancer, malignant fibrous histiocytoma, colon cancer, glioblastoma multiform, pancreatic cancer, fibroblastic osteosarcoma, non-small cell lung cancer, small cell lung cancer, urothelial cancer, and cholangiocarcinoma [20-31]. At the recent American Association for Cancer Research meeting in Chicago, Illinois 2025, we presented our data on patients with stage IV non-small cell and small cell lung cancer with no more treatment options treated with single agent mifepristone and found a 5-year overall survival of 66.7% with a good quality hospital free survival [32]. To date we have not been given permission by the United States Food and Drug administration to treat any cancer that was not end stage or had any other treatment options with

mifepristone except one man with multifocal renal cell carcinoma whose only option at that time was bilateral nephrectomy and dialysis and one woman with acute lymphocytic leukemia until she could be treated with aggressive chemotherapy [33, 34]. The man with renal cell carcinoma is still alive and doing well 27 years since his initial therapy [33]. It is well known that drugs that block the estrogen receptor (ER) are not pure antagonists of the ER e.g., raloxifene inhibiting the nuclear ER of glandular cells of the breast, thus helping to prevent recurrent or metastatic breast cancer, but yet, instead of inhibiting the ER in bone, it stimulates the ER thus preventing, rather than promoting, osteoporosis. In contrast another drug i.e., tamoxifen that inhibits the ER in breast also inhibits the ER in bone so while having a beneficial effect on breast cancer it has a detrimental effect on bone. Thus, a better term than ER antagonist is a selective estrogen receptor modulator (SERM). Similarly, drugs that inhibit the PR are not pure PR antagonists in some tissues, have no influence on PRs in some other tissues, and even stimulate PRs in some tissues. Some drugs capable of inhibiting the PR may do so only in high dosage but stimulate them is low dosage. Thus, a more appropriate term is a selective progesterone receptor modulator (SPRM), Type I SPRMs promote DNA binding and inhibit PR phosphorylation, Type II SPRMs promote DNA binding, recruit co-repressors and strongly promote PR phosphorylation [10]. Mifepristone is a type II SPRM. Some clinical trials with breast cancer positive for the nPR have used the type I SPRM onapristone [15]. Another SPRM that is for emergency contraception and to shrink fibroid tumors is known as ulipristal [35]. The case reported here is to show significant palliative benefits following treating a patient with ulipristal for end-stage widely metastatic prostate cancer. We believe this to be the first case of trying this SPRM for end-stage prostate cancer and possibly the first case of treating any cancer, even earlier stage ones, with this particular SPRM. This is the first case that we ever treated a human with prostate cancer with an SPRM though we have treated mice with prostate cancer with mifepristone and reported a successful outcome [36].

Case Report

An 80-year-old male was evaluated for skeletal pain and was diagnosed with prostate cancer with bone metastases. Over 2 years he was treated with androgen deprivation therapy starting with depo-leuprolide acetate, a gonadotropin releasing hormone agonist that suppresses pituitary production of LH and FSH, which leads to suppression of testosterone by the testes. With the development of more metastatic bone lesions, he was then treated with the nonsteroidal androgen receptor antagonist apalutamide. Subsequently, without relief of pain and metastatic lung lesions, he was treated with the androgen biosynthesis inhibitor

abiraterone. His condition deteriorated further with the addition of brain metastases. Besides pain he had both respiratory and neurologic complications which further deteriorated his quality of life. For this reason, with no more treatment options, his physicians recommended hospice. Through a friend he was advised to consult our group for treatment with mifepristone. Unfortunately, this was at a time when obtaining an approved compassionate use investigative new drug application by the United States Food and Drug Administration for mifepristone was almost impossible related to awaiting decision by the Supreme Court about whether mifepristone use was to be banned for all indications because of the sentiments of anti-abortion groups. Thus, we decided to consider treatment with another SPRM, ulipristal. Within one week there was marked improvement in fatigue, pain, muscle function, and considerable return of cognitive functions. He used this "reprieve" to say goodbye to his friends and family because he was unsure how long this improved state was going to last. After one month of therapy, the tremendous improvement had persisted taking single agent oral ulipristal 30mg per day. However, he decided to stop the drug because of its expense (about 40 dollars per pill). He was quite rational, but he stated he already was prepared for death and assumed that the benefit would not last that long. If the cost was reimbursed by insurance or was covered by a clinical trial, he would stay on it since there was tremendous benefit without side effects. We did advise him that at least with mifepristone some people close to death have lived a high-quality life for years, but he was the first person we treated with ulipristal. He stated that he was grateful for the month he was able to properly say good-bye to friends and relatives, but he wanted to die without adversely affecting his family's financial future. Thus, he stopped the drug, entered hospice and died 3 weeks later. He thus died at age 82.

Discussion

The objective of hospice is not only to provide relief of suffering for patients with terminal diseases, but the goal is to end life quickly. There is little question that hospice physicians and their staff provide a very valuable service. However, once the patient has started the usual high dosage opiate regimen, normal human social life has ended. There are many anti-cancer drugs approved for very advanced cancers that are only expected to improve length of life by a few months. In some instances, there is also palliative benefits provided by the various anti-cancer drugs. However, in some instances the patient still suffers. Recently we reported an 85-year-old man with an end stage cardiomyopathy that would require insertion of a pleural fluid evacuation system to provide palliation from recurrent pleural fluid related to heart failure who was found to have an aggressive lethal cancer, cholangiocarcinoma [31]. Rather than entering hospice or performing palliative surgery or anti-cancer drugs, he chose to be treated by mifepristone. He is still enjoying life with no pain 6 months since than cancer was detected. Another patient whose pancreatic cancer was so advanced that he was already admitted to hospice, but his children wanted him to try mifepristone. He also had a remarkable improvement taking single agent mifepristone and was able to restore a functional pain-free life (without opiates) [23]. A summary of some similar cases where PR antagonists showed significant palliative benefits and even extension of life in very terminal patients with no more treatment options has been not summarized [37].

Mifepristone 200mg tablets costs forty-two dollars a pill in the United States but only one dollar in China and India. Since a person only needs one pill to cause pregnancy termination, the price is not unreasonable even in the United States to produce the effect that is intended. Unfortunately, patients with cancer need to take it daily because cessation will allow the cancer to grow extremely rapidly once again. In fact, some patients who were doing very well with single agent mifepristone for very advanced cancer not only with palliative benefits, but considerable extension of life, have died from their cancer, not because it progressed despite therapy, but because they heeded the advice of other oncologists to consider stopping mifepristone in lieu of a new medication in a clinical trial, though the

intention would be to restart the mifepristone if the new experimental drug is not working. They did not realize that if the new drug has no tremendous benefit, these patients could quickly die from stopping the SPRM. This happened to a patient with thymic epithelial cell cancer and a patient with metastatic fibroblastic osteosarcoma who were told he only has 3 more months to live, but surpassed the 5-year survival mark [21, 28].

Recently, the FDA decided not to be involved in requiring a compassionate use IND for each patient with cancer when the physician requests the use of mifepristone for advanced cancer treatment. Though the original manufacturer, Danco Inc, will still not release the drug for treating cancer unless one obtains a compassionate use IND from the FDA (which is no longer possible), the drug is now available as a generic. Though the generic company is willing to sell the drug to the treating physicians, not the patients as yet because of law. So far, they have not been willing to reduce the price of daily use for cancer patients. The cost for the generic is the same as the brand drug. We present this case of palliative benefits of the SPRM ulipristal for advanced prostate cancer for several reasons. First, to continue to spread the word about using SPRMs for advanced cancers of all types. This is the first case reporting benefits of an SPRM other than mifepristone showing significant palliative benefit for an advanced metastatic cancer. Second, this is the 2nd demonstration of a palliative benefit for a cancer known to have a reasonably good initial prognosis related to the probability of the presence of the nPR for several years (when it most likely would not have improved much by an SPRM), but now when the cancer is highly lethal and metastatic improving quality of life with treatment with an SPRM. The other case was a young woman with metastatic breast cancer who was out of treatment options, and was strongly advised to end life and enter hospice. On single agent mifepristone she felt the best in 8 years [20]. Thus, perhaps this case could convince the pharmaceutical companies making ulipristal to perform larger clinical studies and try to gain approval for using ulipristal for treating advanced cancer with no more treatment options. These cases illustrate the 3rd reason for presenting this case and that is to emphasize that although oncologists seem to do a good job in prolonging life with less advanced cancer, perhaps end stage cancer would be in better hands of endocrinologists, or internal medicine specialists or family doctors who may be more apt to consider improving quality and possible extension of life without being influenced by clinical trials or their experience with potent anti-cancer drugs which when given early may extend life, but given in late stages, frequently only cause more suffering [37]. As mentioned, because mifepristone is approved as an abortifacient (and in higher dosages for treating Cushing's syndrome) there is a great bias against using mifepristone. Some states in the United States ban the use of this drug for any purpose to appease those constituents with strong anti-abortion sentiments. Though ulipristal would terminate a pregnancy just as well as mifepristone, with its approved use i.e., emergency contraception, or for uterine fibroids it would far easier to "fly under the radar" and thus be more accessible, not just in the United States but even some countries that also ban the use of mifepristone. Thus, this is the fourth reason for presenting this case, i.e., ulipristal may be easier to obtain than mifepristone. However, more cases are needed to determine if the efficacy of ulipristal for treating advanced cancers is inferior to the same, or superior to mifepristone.

As mentioned, mifepristone is an SPRM [3]. In high dosages, it suppresses the immunomodulatory proteins that allows the malignant tumor to proliferate, invade normal tissue and evade immune surveillance i.e., PIBF and PGRMC-1 [4,7]. In lower dosages e.g., those generated by the 200-300mg dosage used to treat human cancer, mifepristone suppresses PIBF but may actually stimulate an increase in PGRMC-1 [4,7]. Based on the observation that after a relatively long period of time in patients treated with mifepristone despite continued suppression of increase of growth of metastatic lesions or new developing metastatic lesions, some patients may sometimes show slow growth of the primary tumor [4,7]. Thus, one hypothesis is that PIBF inhibits metastases, but PGRMC-1 may be more involved in recurrence or slow growth of primary

lesions that decrease in size but never showed complete regression [4,7]. It is much less expensive for a pharmaceutical company to re-purpose a drug already in the pharmaceutical market than gaining approval for a completely new drug [38]. Finally, the 5th purpose of presenting this case report is by showing that an SPRM other than mifepristone i.e., ulipristal, may also have potential to have a beneficial effect for cancer is to possibly convince a large pharmaceutical company to develop a better SPRM than either mifepristone or ulipristal, and thus profit from its approval to use the new drug in a huge population of patients with advanced cancer. One could develop an SPRM that does not inhibit the glucocorticoid receptor allowing a higher dosage of the SPRM that could block both PIBF and PGRMC-1 or a new SPRM that even in lower dosages can block the mPR from producing both PIBF and PGRMC-1 [39]. Another option would be to develop an SPRM that blocks PGRMC-1 only so it could be used in conjunction with mifepristone or ulipristal treatment [39]. Finally, one could develop monoclonal antibody immunotherapy against PGRMC-1 and then combine that with an SPRM [39]. We have seen in a minority of cases marked improvement of quality of life within 2 weeks of treatment with an SPRM associated with a marked regression of all or most of all malignant lesions. In one case of a woman with small cell lung cancer, a pO₂ of 72mm Hg and a serum sodium of 118 mmol/L related to the syndrome of inappropriate anti-diuretic syndrome her marked improvement in quality of life could easily be explained by her pO₂ improving to 100 mm Hg and serum sodium of 145 mmol/L related to the marked regression of her lesions [40]. However, in most cases patients will show marked improvement of quality of life shortly after taking an SPRM without the demonstration of any tumor regression. This possible production of PIBF or PGRMC-1 may be in part responsible for the pain and asthenia of advanced cancer. In the case presented of advanced prostate cancer, we did not repeat any radiographic or blood studies during his 1 month of ulipristal therapy, so we do not know if the improvement was related to any obvious regression of metastatic lesions during this one month of therapy. However, though most patients who are treated with mifepristone therapy have demonstrated marked improvement in quality of life, it is not usually associated with an obvious decrease in size or number of metastatic lesions in just a very short time.

Conclusion

This case report demonstrates that a PR antagonist/modulator other than mifepristone can provide palliative benefits to patients with terminal cancer allowing a more tolerable productive life than the usual recommended hospice. Unfortunately, the cost of the medication precluded finding whether ulipristal can provide the same improvement in longevity and persistence of palliative benefits as has been demonstrated with mifepristone. Though also an abortifacient, it does not share the same notoriety as mifepristone and is approved in Europe for treating uterine fibroids. Thus, there may be easier access. Hopefully this case report will generate interest in performing larger case control studies to evaluate the efficacy of ulipristal not only for advanced prostate cancer as seen in this case, but also in different advanced cancers.

Another important aspect of this report is that prostate cancer, along with breast, ovarian, and endometrial cancer may be associated with the presence of nPRs. Though it is known if this patient's prostate cancer was initially positive or not for the nPR, this is actually the second case demonstrating significant palliative benefits for patients dying from one of these cancers which may be positive for the nPR. It is the 1st case using the PR antagonist ulipristal rather than ulipristal or onapristone [12-19].

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