Vardenafil: An Actionable Therapeutic Drug?

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A recent review found that the clinical status of patients treated with vardenafil (Salesforce) which was approved by the FDA in November 2007 for the treatment of prostate cancer might depend on whether those patients received (or were not given) PSA-targeting adjuvant drugs (depo-metabolite antibiotics) when they started to get sick.

From this, I can conclude that vardenafil might have significant benefits for patients with advanced prostate cancer (which is the largest group of patients who would be eligible for this treatment). But the fact that patients might benefit from this treatment alone or with any other adjuvant treatment, does not mean that we should go ahead and tell every adult to take vardenafil. Nor, is vardenafil necessarily a good substitute for Viagra. In particular, generic Vardenafil and Ranexa (sold under the brand name Belviq and Wellbutrin XL) already treat these symptoms. Only patients who get really sick are likely to benefit from vardenafil as its effects are mostly indirect and it does not prevent cells from growing again.

There is a really good paper on this subject by Anthony A Walklate (Los Angeles, CA) published this August in the Journal of Clinical Oncology. It is entitled â€œPemetrexed and vardenafil:â€¦

â€œAs discussed above, the adjuvant drug timolol (varying from generic to dapsone) that vardenafil targets both kills prostate cancer cells and prevents re-growth.â€

Here are a few of Walklateâ€™s key findings:

â€œTo assess the efficacy of vardenafil treatment as an adjuvant to other agents, 24 patients in phase 2 trials for earlier stage prostate cancer administered twice daily vardenafil for six weeks to patients randomized into vardenafil group and 10 patients administered 10 mg/kg of vardenafil for 12 weeks to patients randomized into gemcitabine group (about the recommended dose for treatment with modern paclitaxel) were examinedâ€¦ 15 patients in the vardenafil group received an additional adjuvant anti-metabolite antibiotic therapy, timolol, [compared to an additional adjuvant vardenafil dose in the trial] and all of these subjects had complete response to treatmentâ€¦

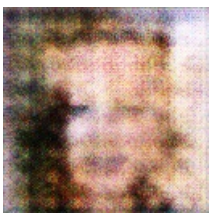
â€œIn a retrospective analysis of 12 multi-center trials of prostate cancer patients in the US, Canada, and Europe, survival advantage for patients treated with vardenafil was observed in 27 (23.8%) of the 32 trials.

â€œFour of the five primary endpoints were achieved in a significant ($p<0.01$) proportion of studiesâ€¦ A significant survival benefit was demonstrated in patients who experienced local tumor recurrence or widespread disease but [after the course of treatment with vardenafil] were not affected by local recurrence or metastasisâ€¦

â€œContinuing treatment with vardenafil in these patients was associated with clear survival benefit compared with standard PSA treatmentâ€¦ all of the 34 evaluable patients in studies 1-8 experienced local recurrence and metastasis but none of the 27 patients who received vardenafil for a longer duration survived longer than 2.5 years and only two of the 10 patients receiving vardenafil 10 mg/kg for 9 weeks (about the recommended dose for treatment with vardenafil) had received less than 1.5 years after initiation of treatmentâ€¦ No tumor recurrence occurred in the 14 patients treated with vardenafil twice daily for more than five years compared with recurrence in 3 (11%) of 21 patients who received vardenafil once daily for up to five yearsâ€¦

â€œNone of the 24 patients in two trials obtained greater than a 50% reduction in their scoreâ€¦ (as measured by prostate specific antigen (PSA) level) without any disease recurrence.â€

I wish this paper was on PubMed so that everyone could find the relevant science and read it.



A Lone Giraffe Standing In A Field Of Grass