


Efficacy and Safety of Combination Comprising Tamsulosin and PDE5-Is, Relative to Monotherapies, in Treating Lower Urinary Tract Symptoms and Erectile Dysfunction Associated With Benign Prostatic Hyperplasia: A Meta-Analysis

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Dear Editor in Chief,

I browsed again the study published by Sun et al. (2020) in the latest issue of benign prostatic hyperplasia (BPH). The meta-analysis was conducted to compare the combination of Tamsulosin and PDE5-Is versus monotherapy of Tamsulosin or PDE5-Is in treating lower urinary symptoms (LUTS) and erectile dysfunction (ED) associated with BPH. However, the authors have made some mistakes and I sincerely felt it was my honor to share my perspective with the colleagues.

It is listed as follows:

1. All the included literatures are considered to be low risk in the original article. As stated in the original paper: "Each RCT was classified based on the following quality assessment criteria: (a) had low potential of bias for meeting almost all the quality criteria," Sebastianelli et al. (2019) do not clearly mention the method of blinding and Karami et al. (2016) is single-blind, so the quality assessment should not be low risk.
2. Heterogeneity is obvious in this article. The dosage of Tadalafil varies from different studies resulting in huge heterogeneity, as is mentioned in the limitations part by Sun et al. (2020) And the inclusion criteria are distinct among the included RCTs. Bechara et al. (2008), Fawzi et al. (2017), Nagasubramanian et al. (2020), and Singh et al. (2014) recruited patients with LUTS ± ED, while Karami et al. (2016) and Sebastianelli et al. (2019) constrained the inclusive patients with LUTS and ED simultaneously. However, the authors don't demonstrate the outcomes of sensitivity analysis and subgroup analysis, which is quite necessary in my perspective. These problems inevitably

lower the credibility of results of the meta-analysis.

3. Among all the included studies, only one article (Fawzi et al., 2017) administrates Sildenafil and Tamsulosin in combination group while others have Tadalafil and Tamsulosin. It remains to be one of the major sources of heterogeneity, so I prefer to set the inclusion criteria as administration with the combination therapy of Tadalafil and Tamsulosin versus monotherapy of Tadalafil or Tamsulosin and this article is exclusive.
4. Significant variation of baseline characteristic is identified in the studies. The data may be not comparable.
5. It is stated in the conclusion in the original paper: "our findings indicate that a combination of tamsulosin and PDE5-Is is superior to individual tamsulosin and PDE5-Is monotherapy, with regard to improving LUTS and ED secondary to BPH." However, the forest plots don't show the superiority of PDE5-Is compared to combination therapy as the authors point out in the result part. The description lacks rigor.
6. The original paper states that "Results revealed no significant differences between the combination and tamsulosin groups (OR = 1.47, 95% CI [0.76, 2.84], $P = .25$; Figure 6c) as well as the

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combination and PDE5-Is groups (OR = 1.69, 95% CI [1.01, 2.84], $P = .05$; Figure 7c).” Anyway, the 95% CI is from 1.01 to 2.84 in terms of comparison of combination and PDE5-Is groups, which illustrates that the combination therapy had a significantly higher incidence of discontinuation due to pain and AEs than PDE5-Is.

7. The keywords are composed of quality of life, general health and wellness, sexual health, sexuality, sexual dysfunction, sexuality, sexual disorders, and sexuality. However, I think the keywords shouldn't be confined to sexual aspect. Besides lower urinary tract symptoms, benign prostate hyperplasia, phosphodiesterase 5 inhibitors, and adrenergic alpha-1 receptor antagonists are also the main aspects in the paper.

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