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A Call to Action to Review the USPSTF's Recommendation for Testicular Self-Examination

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Abstract

We urge the United States Preventive Services Task Force (USPSTF) to call for a formal review of the evidence regarding testicular self-examination (TSE). Twelve years have since passed since the evidence was last formally analyzed where normally re-reviews occur in 5-year cycles. If they would decide to move forward with this action, we ask for the USPSTF to review their methods for establishing recommendations to optimize their rating system operationalization process. Finally, emerging evidence demonstrates a net positive effect of TSE. This stands in contrast to the assertions of TSE's supposed harm that is prevalent in the literature as well as the rationale behind the USPSTF's "D" rating of TSE.

Keywords

testicular self-exam, general health and wellness, testicular cancer, oncology/cancer, policy and law, health education, general health and wellness, health information, general health and wellness

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Overview of the Issue

Testicular cancer (TC) is the most common malignancy in males ages 20 to 34 years, with a median age of diagnosis of 33 (National Cancer Institute [NCI], 2021). The American Cancer Society (ACS, 2022) predicts 9,910 new cases and 460 deaths from TC in 2022. As of 2021, there is a trend toward increasing incidence (rising an average of 0.7% a year) and a stable mortality rate of TC worldwide among most male populations (NCI, 2021). There are, however, glaring disparities in outcomes among minority males; the U.S. non-White populations tend to have increased incidence and higher mortality rates as well as worse survivorship outcomes compared with their White counterparts (Ghazarian & McGlynn, 2020; Li et al., 2020).

The etiology of TC is unknown (Saab et al., 2018). Males with the highest risk for developing TC, though, possess several risk factors: cryptorchidism, family history, and/or previous diagnosis of TC (Fadich et al., 2018). Scientific evidence is too sparse, however, to gauge the magnitude of risk for each of these factors. A more focused approach at producing reliable, quality, and abundant evidence is necessary for any type of conclusive statement to be made about causal factors of TC.

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TC is indeed "curable," but that term needs to be used cautiously. The United States Preventive Services Task Force's (USPSTF) "D" recommendation is cited as appropriate due to the low incidence of testicular cancer and high survival rates; however, this reasoning does not account for the considerable potential long-term toxicities and reductions in health-related quality of life (HRQoL) associated with treatment for advanced disease. Although survivability of the disease is of utmost importance, so too is post-treatment HRQoL. The survival rate at all stages is 95%, with local stage at 99%, regional stage at 96%, and distant stage at 73% (ACS, 2022). An individual's chance of dying of TC is very low, even at an advanced stage, but this does not necessarily mean HRQoL will be high post-treatment, especially if the individual received chemotherapy and/or radiation (Kim et al., 2011; Schepisi et al., 2019). Men who have received chemotherapy and/or radiation are known to harbor significantly increased risks of long-term toxicity, including cardiac disease, renal impairment, and increased risk of secondary malignancies (Kim et al., 2011). Depending on the assigned treatment, males with later-stage discovery (Stages 2–3) have worse long-term health outcomes compared with those cases discovered earlier (Xu et al., 2020). Early detection of the disease is a large contributor to just how "curable" the disease can be, in the sense of survivability, HRQoL, and risk of future health problems.

The first signs and symptoms of TC are mostly accidental self-discoveries (USPSTF, 2011). Other primary detection methods include intimate partner discovery or clinician palpation. The USPSTF, however, has consistently recommended against routine examination in asymptomatic males, particularly testicular self-examination (TSE), as they claim the harms outweigh the benefits. The USPSTF has thus granted TSE a "D" rating, recommending *against* this behavior among males. This therein lies our concern.

Our Petition

In the spirit of transparency with this commentary's intent, we plainly state, with conviction, that the USPSTF needs to make a formal call of evidence review for TSE recommendation. We have come to the conclusion that a formal review is needed for three reasons, of which we will present below: (1) the suggested interval between reviews is 7 years past due, (2) the current rating for TSE does not adhere to the guidelines put forth by the USPSTF, and (3) emerging evidence on the harm/benefit corollary. Furthermore, we conclude that the recommendation for TSE should be an "I," with a call to produce more acceptable evidence to move the needle one way or the other in this debate. No ethics approval has been sought for the creation of this opinion piece as no human subjects were involved in the creation of this specific summary.

Reason 1

The last formal review of the evidence for TSE's effectiveness in reducing TC mortality was approximately 12 years ago, although the USPSTF states that a review should be conducted every 5 years (Institute of Medicine, 2011). We are 7 years past where a review should have happened, which makes a review of TSE technically two review cycles behind.

We have not been silent in those years since the USPSTF's last formal call. This current commentary, in fact, is not the first request for the USPSTF to review the evidence and make a call for evidence review. There have been several public pleas by members of the academy, clinical practice, and male health think tanks for the USPSTF to take up the call to review the evidence again (for example, see Fadich et al., 2018; Rovito et al., 2016; Rovito & Nangia, 2019). Each piece concluded with a call to action for the USPSTF to rethink their "D" rating recommendation for TSE and to make the call for a formal review of the evidence. There has been no response from the USPSTF, nor any indication that a formal call for evidence review is underway, as of the time of this writing. In fact, the official webpage dedicated to the Task Force's TSE recommendation has not been updated with any related information (at least to these authors' knowledge) since 2011 (USPSTF, 2011).

Reason 2

Evidence? What Evidence?

The USPSTF firmly, and consistently, grants TSE a "D" rating recommendation, suggesting that existing evidence clearly demonstrates that TSE is harmful. The reason and rationale behind this "D" rating, however, remains controversial with many TC experts and men's health advocates. A lack of evidence of benefit is *not* the same as evidence of a lack of benefit. Due to the complexity and depth of this debate, it is worth providing some background to the reader with the historical timeline surrounding TSE's rating granted by the USPSTF.

In 1996, the USPSTF (1996) gave screening for TC (including both TSE and clinical examination) a "C" rating, indicating the potential harms and benefits were too close to justify a general recommendation. Eight years later, the USPSTF concluded with moderate certainty that the recommendation be changed from a "C" to a "D," thus recommending against routine TC screening for asymptomatic patients (Calonge, 2005). The Task Force admitted that no new evidence was found showing the

efficacy of TSE on reducing mortality and that any potential benefits were exceeded by the harms of screening (i.e., false-positives, anxiety, and harms from interventions; Calonge, 2005). This is a very important, and albeit contentious, statement to make as there was no evidence produced showcasing neither benefit nor harm as a result of practicing TSE. The change in recommendation therefore appears to be made on the basis of expert opinion rather than new clinical evidence.

Grade definitions and criteria used to evaluate the strength of evidence for recommendations were modified in May of 2007 (e.g., practice recommendations were associated with each grade and defined levels of certainty regarding net benefit were provided for). The current TSE recommendation originates from an evidence-based review conducted in 2009 by Lin and Sharangpani (2010) that found no new evidence that "would warrant a change" from the 2004 recommendation. Lin and Sharangpani (2010) posited that although the current recommendation should remain unaltered, the new studies on TSE should serve as a reminder for clinicians to keep TC as part of their differential diagnoses. What is most important here, again, is that Lin and Sharangpani (2010) not only failed to identify any evidence discussing the benefits or harms of TC screening. Just as in 2004, a recommendation was provided without any evidence to justify that decision.

Rovito et al. (2016) indicate that if you follow the USPSTF's own methodological framework, one will logically conclude that the rating for TSE should be an "I," not a "D," indicating that not enough information currently exists to make a judgment on either side of the harm/benefit corollary. The American Cancer Society has similar sentiments as they suggest that "because regular testicular self-exams have not been studied enough to know if they reduce the death rate from this cancer, the ACS does not have a recommendation on regular testicular self-exams for all men" (ACS, 2018). Others do too, including the American Urological Association (AUA, 2022), who list TSE on their men's health checklist materials but asterisk the behavior with the caveat: "Level of evidence insufficient/poor (USPSTF) but may be indicated with symptoms and/or higher risk cases." This oddly nebulous stance on testicular exams has existed for quite some time with no real progress on achieving some sort of consensus position on the issue.

Is There Room to Maneuver?

The USPSTF indicates that if evidence is lacking, alternate forms of data are permissible to supplement the existing data pool. Lin and Sharangpani's (2010) review did not include any articles that fit the USPSTF criteria. Of the 113 articles that loosely fit their search criteria, the authors chose three studies to make a recommendation on whether or not males should perform TSE. According to Rovito et al. (2018), those selected pieces of evidence were wholly inadequate to provide a basis for supporting or rejecting any recommendation. For example, Lin and Sharangpani (2010) included a study whose sample consisted of only males diagnosed with testicular microlithiasis, which is problematic as testicular microlithiasis is contested in the literature as a risk factor for TC (Barbonetti et al., 2019; Sevilla & Gonzales, 2022).

This leads to a larger concern: The leniency to include evidence that does not fit within the criteria set forth by the USPSTF has the potential to become a slippery slope scenario if we are not clear on the parameters of inclusion/exclusion. Not only can the types of acceptable designs expand to include nonrandomized controlled trials (of which we are generally supportive), but the topics themselves may become more flexible (of which we are wary, like the example of testicular microlithiasis). As the facilitation of fully-powered randomized controlled trials to determine whether TSE affects TC mortality is likely not feasible due to low event rate and the requirement of a prohibitively large sample size, we would have to be supportive of including other designs (i.e., retrospective cohort designs, case-control studies, large-scale ecological studies, among others) that need to be incorporated into the evidence base. We should be wary, however, of the breadth of topics allowable into the recommendation calculus. We can all agree more evidence is needed but we also need to be flexible with how that evidence is produced while continuing to keep data quality among our highest priorities.

Language Matters

Another discrepancy lies within the grading and wording of the USPSTF. The use of language is a very important factor in the debate of whether or not to recommend TSE to males. The USPSTF uses three categories for quality of evidence, namely, *good, fair*, and *poor*, and subsequently makes recommendation statements with a level of certainty (*high, moderate, low*) based on such evidence.

Good evidence contains consistent results from studies that are well-designed, generalizable, and that directly assess the effects of the preventive measures in question. *Fair* evidence is defined as evidence sufficient enough "to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes" (Calonge, 2005). *Poor* evidence does not sufficiently assess the effects on health outcomes.

To bring these definitions to life, Lin and Sharangpani (2010) reaffirmed the previous "D" rating recommendation with *moderate* to *high* certainty, implying there is *sufficient* evidence to recommend against TSE. *Moderate* certainty is held back by constraints, however; these constraint factors can include the quality, consistency, generalizability, and coherence of the supporting studies (Agency for Healthcare Research and Quality, 2012). It is highly concerning that the *sufficiency* of evidence is nowhere operationalized. What are the criteria for insufficiency? Is it left up to the discretion of the researcher to define? Are USPSTF's definitions similar to other professional bodies in TC research?

Reason 3

As mentioned previously, we are fully cognizant that to produce the data necessary to fit the USPSTF criteria would be extremely difficult given the strained resources available to be able to conduct such a rigorous design to supply appropriate data. Having insufficient evidence has repeatedly been the primary reason for why the USPSTF consistently comes down on the side of not recommending TSE. We need to be open to including other designs that can contribute to building an evidence base to help break the impasse of not having data on either side of the harm/benefit corollary.

The exploratory analysis by Rovito et al. (2022) aimed to provide baseline evidence of the possible association between the practice of TSE and the stage of TC diagnosis. Although the evidence stems from a cross-sectional study design, as opposed to a randomized controlled trial, the article does indeed make an indirect claim that TSE has the potential to improve quality of life and decrease TC mortality, particularly among adolescents and young adults. The authors indicate that those survivors, generally, who practiced regular TSE before TC diagnosis had a stronger association with earlier stage diagnosis than those who did not practice regular TSE. Of course, these results are correlational, not causal, but it is evidence nonetheless.

Conclusion

Here are some closing thoughts and recommendations we have concerning TSE and the USPSTF's current "D" rating recommendation:

1. The USPSTF needs to make a call for a formal review of the evidence to reassess the current rating. It has been 12 years. We need to show good faith in making regular reviews of the evidence every 5 years, as the USPSTF suggests. Now is the time to make this happen.
2. There are inconsistencies with the logic and the methodology that led to the USPSTF's conclusion and reaffirmation of the "D" rating recommendation for TSE. Not only do the current guidelines use ~15-year-old literature, but the data they offer as evidence of TSE's harm are inappropriate to make any firm conclusion. There are no data indicating any quantifiable harm from conducting regular TSE, therefore rendering the "D" rating recommendation erroneous. How can the harm outweigh the benefits if no one ever provided evidence of such harm? Are the potential harms of anxiety and distress from doing a self-exam outweighed by the potential long-term toxicities and health system spending that result from treatment of Stage II and III testicular cancer? Therein lies a question, among others, we all have to ask ourselves as we begin to operationalize what harm truly means.
3. Despite the continued negative reception TSE received from the USPSTF, the behavior is widely promoted among men's health practitioners. In fact, TSE is known to have benefit beyond detecting cancer, most notably benign testicular disorders (Saab et al., 2019), hernias, certain sexually transmitted infections (e.g., genital warts), among other health issues (Rovito et al., 2018). But, in all fairness, no large-scale, fully-powered trials exist to demonstrate TSE's ability to lower TC mortality rates. There are data emerging, though, that are beginning to empirically show TSE's effectiveness (i.e., Rovito et al., 2022). We need to encourage more of these studies.
4. To have any other rating but an "I," one of two things need to happen: (a) we increase the amount of funding available to conduct fully-powered trials to produce the evidence warranted by the Task Force to make any firm conclusive rating or (b) we expand the type of evidence allowable in the review (see #3 above). These authors recommend expanding the type of evidence to be included in the analysis but caution on how far we may deviate from the central question at hand.
5. The USPSTF recommendations matter as they affect practice, which in turn affects patient health outcomes. There needs to be, naturally, a renewed emphasis on which words are being used to operationalize select terms for their grading systems (i.e., *fair, sufficient, poor*, among others). The way we wield our prose can affect many people. We urge caution.

We urge the USPSTF to call for a formal review of the evidence regarding TSE. It is well past the standard

5-year mark of re-review (the preferred interval time between reviews). In fact, it has been over a decade since the evidence was last formally analyzed. If they would decide to move forward with this action, we also implore the USPSTF to review their methods for establishing recommendations. Their most recent TSE review is suspect to systematic error, most evidently in the operationalization of key rating system nomenclature (see Rovito et al., 2016). We urge a complete review of said methods to ensure data quality and that the guidelines provide for clear, unmistakable authority on which recommendation is granted and the transparent, evidence-informed reasoning behind the decision.

Finally, emerging evidence ushers in the possibility of a break in the harm–benefit debate (e.g., Rovito et al., 2022). This infusion of new information demonstrates a net positive effect of TSE was measured as compared with the more standard, conjectured assertions of TSE's supposed harm that is prevalent in the literature. We encourage more of this research to help add to the current evidence base.

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