Preventive Medicine Reports 3 (2016) 361–366

Contents lists available at ScienceDirect

Preventive Medicine Reports

journal homepage: http://ees.elsevier.com/pmedr

Review Article

From 'D' to 'I': A critique of the current United States preventive services task force recommendation for testicular cancer screening

Michael J. Rovito [a,*], Janna Manjelievskaia [b], James E. Leone [c], Michael J. Lutz [d], Ajay Nangia [e]

[a] College of Health and Public Affairs, Department of Health Professions, University of Central Florida, 12805 Pegasus Drive, HPA1 Room 269, Orlando, FL 32828, United States
[b] Mayes College of Healthcare Business and Policy, Department of Health Policy and Public Health, University of the Sciences in Philadelphia, 600 S 43rd St, Philadelphia, PA 19104, United States
[c] Department of Movement Arts, Health Promotion, and Leisure Studies, Bridgewater State University, Bridgewater, MA 02325, United States
[d] Michigan Institute of Urology, 6900 Orchard Lake Rd. West Bloomfield, MI 48322, United States
[e] Dept. of Urology, University of Kansas Medical Center, 3901 Rainbow Blvd, Kansas City, KS 66160, United States

ARTICLE INFO

Article history:
Received 3 April 2016
Accepted 20 April 2016
Available online 21 April 2016

Keywords:
Self-examination
Testicular neoplasms
Early detection of cancer
Practice guidelines as topic

ABSTRACT

In 2004, the United States Preventive Services Task Force (USPSTF) gave testicular cancer (TCa) screening a 'D' recommendation, discouraging the use of this preventive service. The USPSTF suggested that screening, inclusive of testicular self-examination (TSE) and clinician examination, does not reduce TCa mortality rates and that the high risk of false positives could serve as a detriment to patient quality of life. Others suggests that TCa screening is ineffective at detecting early-stage cases of TCa and readily highlights a lack of empirical evidence demonstrating said efficacy. These assertions, however, stand in stark contrast to the widely held support of TCa screening among practicing public health professionals, advocacy groups, and clinicians.

In this present study, a review was conducted of the methods and processes used by the USPSTF in their 2011 reaffirmation of the 'D' grade recommendation. The evidence base and commentary offered as to why TSE, as part of the overall recommendation for TCa screening, was given a 'D' grade were analyzed for logical reasoning and methodological rigor.

Considering the methodological flaws and the veritable lack of evidence needed to grant a conclusive recommendation, the question is raised if the current 'D' grade for TCa screening (i.e. discourage the use of said service) should be changed to an 'I' statement (i.e. the balance of benefits and harms is indeterminate). Therefore the purpose of this paper is to present the evidence of TCa screening in the context of efficacy and prevention in order for the field to reassess its relative value.

Contents

* Corresponding author at: University of Central Florida, Department of Health Professions, 12805 Pegasus Drive, HPA1 Room 269, Orlando, FL 32816, United States.

http://dx.doi.org/10.1016/j.pmedr.2016.04.006

1. Introduction

The United States Preventive Services Task Force (USPSTF, 2004; 2011) suggests that there is a lack of available evidence demonstrating how routine testicular cancer (TCa) screening (including both testicular self-examination [TSE] and clinician examination) has greater yield and/or accuracy for detecting TCa at more curable stages (USPSTF, 2011). The Task Force also claims that, generally, TCa is >90% curable and that TCa screening is unlikely to offer meaningful health benefits. One adverse outcome readily offered as evidence that TCa screening (i.e. TSE) should not be recommended is the potential onset of anxiety associated with a false-positive result. Essentially, according to the USPSTF, among others (e.g. Lin and Sharangpani, 2010), TSE and clinician examinations have limited value. This position, however, is grounded in limited evidence and fails to take into account the potential benefits of TCa screening.

Incidence rates of TCa are rising among the 15 to 54 year-old demographic, but primarily affect those under the age of 40 (Kennett et al., 2014). Howlader et al. (2013) indicates that TCa cases have been rising ~1% each year in the past decade. As there are few known risk factors for TCa outside of age (Znaor et al., 2014), cryptorchidism (Lip et al., 2013), or family history of the disease (Kharazmi et al., 2015), it is wise to operate under the assumption that all males are at-risk for developing the disease. Those males who lay claim to one or more of the aforementioned risk-factors could be labeled 'high-risk', but the relationship between TCa manifestation and said factors remain spurious at best due to the lack of research conducted highlighting those associations.

It is the collective wisdom of these authors that all males receive multifactorial benefits from regular TSE performance, inclusive of decreased mortality from the disease (see Rovito et al., 2015). The issue, however, for both sides of this debate, but more so serving as the onus for the anti-TSE camp, that when speaking exclusively about TCa mortality reduction, there are zero studies conducted among asymptomatic males demonstrating the harms and/or benefits received from testicular examination, either clinician or self-examination. In essence, the evidence is insufficient to point one way or the other. Hence, the current D-grade recommendation, according to the definitions used by the Task Force themselves, is erroneously granted to TSE. Due to the dearth of evidence between physical examination of testicles as a preventive measure to decrease TCa mortality, it is more appropriate to grant an I-statement recommendation.

The following discussion will highlight the spurious nature of the data used by the USPSTF to discourage TCa screening, as well as the inconsistencies in methodological rigor used to create its current 'D' grade recommendation. As the criteria used to create ratings are limited in scope with some having little, if any, relevance in the decision-making process to determine TCa screening's worth, these authors advocate for a reassessment of the current methodology used when creating recommendations in the absence of solid evidence. Finally, these authors question the appropriateness of the USPSTF (2011) 'D' grade for TCa screening and lend support for Rovito (2016) argument for the inclusion of TSE in a standard of care as the potential harms associated with the 'D' grade are a cause for concern for male lifespan health.

1.1. Overview of the recommendation process and current support

Recommendations made by the USPSTF (2011) are based on explicit criteria. An independent panel of experts in primary care and prevention systematically review the available evidence of effectiveness on a particular topic and develop recommendations for clinical preventive services accordingly (Agency of Healthcare Research and Quality, 2012). Other experts in the field outside of primary care are invited to provide peer review of existing evidence summaries and draft recommendations (Siu et al., 2015). USPSTF panels tend to be conservative in their recommendation statements, relying solely on available scientific evidence. Their approach differs from other bodies that develop clinical practice guidelines (CPGs), which may rely on expert opinion and clinical judgment in the absence of randomized controlled trials (RCTs) (Goolsby, 2002).

One of the main challenges in developing recommendations is deciding which position to take when the evidence is inadequate and lacking, as is the case for TCa screening, and more specifically, TSE. RCTs are generally regarded as the strongest evidence base for providing an intervention by the USPSTF (2011). Yet, even the Task Force acknowledges that this standard of evidence is unattainable for a majority of clinical preventive services. Recognizing this limitation, non-RCT study designs also are included in the evidence base used by the USPSTF (Petitti et al., 2009). The USPSTF (2011) considers indirect evidence in such cases where a 'chain of evidence' is created within an analytic framework to inform the recommendation (Petitti et al., 2009).

Some have advocated that the Task Force provide 'clinical options' (especially if the harms and costs with performing a particular service are minimal) or that services, which have not been adequately studied, should not be recommended (Woolf and Atkins, 2001). Some suggest that a neutral stance should be taken (meaning not recommending for or against a service) until better evidence is available or that those who are deemed high-risk should be informed of the benefits of performing regular TSE (Woolf and Atkins, 2001; American Urological Association [AUA], 2014). Others explicitly state (i.e. the Society for Adolescent Health and Medicine, 2012) their support for TCa screening or suggest that identified high-risk males (i.e. Caucasian race, being between the ages of 15–40, family history of the disease, and/or the occurrence of cryptorchidism) should 'seriously' consider performing monthly exams (ACS, 2015).

1.2. Past and present USPSTF recommendations for TCa screening

Calonge (2005) states that in 1996, the USPSTF found that existing evidence to recommend either for or against routine screening for TCa was insufficient as it pertains to asymptomatic men. TCa screening was given a 'C' grade, indicating the reviewing body was not in a position to recommend promoting the behavior or not, thus leaving the decision to the patient and provider. The reviewers included a caveat that for males who were deemed high-risk for TCa, discussions about screening (either TSE or physician exams) can be carried out. In other words, there was insufficient evidence to fully commit to a more positive or more negative TSE recommendation. If, however, a practitioner identifies a male at high risk for developing TCa, then a conversation about TSE is permissible, which is much akin to the AUA's (2014) current position.

The USPSTF (2013) grade definitions have since changed, where a 'C' grade currently indicates that the service should be offered to select patients depending on individual circumstances. Consequently, the USPSTF reassessed the 'C' grade for TCa screening in 2004 and came to the conclusion that they found at least *fair* evidence that it (i.e. TSE) is ineffective and that the harms outweigh the benefits. They specifically argued that no evidence has been produced from appropriate study designs (i.e. RCTs) demonstrating a significant decrease in TCa mortality stemming from the promotion of screening among asymptomatic males. They gave TCa screening a 'D' grade, which is defined as "moderate or high certainty that the service has no net benefit and that the harms outweigh the benefits" (USPSTF, 2013).

A 2008 reaffirmation request brought about Lin and Sharangpani's (2010) rubberstamping of the TCa screening 'D' grade. The authors based their decision upon the high cure rates of TCa (even in later stages of the disease), the potential for false-positive anxiety, the lack of evidence demonstrating TCa screening's effectiveness in reducing mortality, and the potential of increasing costs due to confirmatory procedures (i.e. ultrasound, biopsies, etc.). In 2011, the USPSTF reissued the 'D' grade for the provision of TCa screening by self- or clinician examination.