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Unnecessary free PSA test requests and assessment of the effectiveness of preventive activities

Gereksiz serbest PSA test istemleri ve önleyici faaliyetlerin etkinliğinin değerlendirilmesi

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Abstract

Purpose: The aim of our work is to determine unnecessary fPSA test requests according to the European Association of Urology, European Society for Radiotherapy & Oncology guideline (EAPS-ESTRO-SIOG) and to assess the effectiveness of preventive actions we have made due to unnecessary test order.

Materials and methods: The use of fPSA/tPSA ratio in patients with a serum tPSA level above than 10 ng/mL or below than 4 ng/mL is considered clinically insignificant according to guidelines. Measurement uncertainty for tPSA was calculated as ±15.49%. The limit values (4 and 10 ng/mL)were expanded according to uncertainty value. fPSA ordered in patients with tPSA levels above than 11.54 ng/mL or below than 3.38 ng/mL were considered unnecessary. In addition, if the patient did not have a tPSA test previously performed in another laboratory, the requested fPSA tests in patients without tPSA in our laboratory was evaluated as unnecessary. An informational message has been added to the hospital information system regarding the guideline recommendation. Unnecessary fPSA tests in six months period before and after adding the information message were evaluated.

Results: The number of unnecessary fPSA test significantly decreased in the six-month term after the addition of information note ($p<0.05$). The fPSA test was not requested without the tPSA test in 6 month period after the addition of the information note.

Conclusion: It is important to use the rules and algorithms mentioned in the guidelines when ordering the test. The results of our study suggest that the addition of an informative message according to the guideline recommendation to the hospital information system can reduce the unnecessary test order.

Anahtar Kelimeler: Unnecessary test, free PSA, laboratory costs, pre-analytical phase.

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Özet

Amaç: Çalışmamızın amacı, Prostat Kanseri Avrupa Üroloji Derneği - Avrupa Teropotik Radyoloji ve Onkoloji Derneği - Uluslararası Geriatrik Onkoloji Derneği kılavuzuna (EAPS-ESTRO-SIOG) kılavuzuna göre gereksiz istenen fPSA testlerini belirlemek ve gereksiz test istemleri için yaptığımız önleyici faaliyetlerin etkinliğini değerlendirmektir.

Gereç ve yöntem: Serum tPSA düzeyi 10 ng/mL'den büyük ya da 4 ng/mL'ten küçük olan hastalarda fPSA/tPSA oranının kullanımı kılavuzlara göre klinik olarak önemsiz kabul edilmektedir. tPSA için ölçüm belirsizliği ±%15,49 olarak hesaplandı. Belirsizlik değerine göre sınır değerler (4 ve 10 ng/mL) genişletildi. tPSA düzeyi 3,38'den küçük ya da 11,54 ng/mL'den büyük olan hastalarda yapılan fPSA istemleri gereksiz istem kabul edildi. Daha önce başka bir laboratuvarda tPSA testi çalışılmamış hastalarda tPSA testi olmadan yapılan fPSA test istemleri gereksiz olarak değerlendirildi. Hastane bilgi sistemine rehber önerilerini içeren bilgilendirme mesajı eklendi. Bilgi mesajı eklemeden önceki ve sonraki 6 aylık dönemde istenen gereksiz fPSA testleri değerlendirildi.

Bulgular: Bilgi mesajı eklendikten sonraki 6 aylık dönemde gereksiz istenen fPSA test sayısı anlamlı olarak azaldı ($p<0,05$). Bilgilendirme mesajının eklenmesinden sonraki 6 aylık dönemde tPSA test istemi olmadan fPSA test istemi yapılmadı.

Sonuç: Test istemleri yapılırken kılavuzda belirtilen kuralların ve algoritmaların kullanılması oldukça önemlidir. Çalışmamızın sonuçları hastane bilgi sistemine kılavuz önerilerine göre bilgilendirme mesajı eklenmesinin gereksiz test istemlerini azaltabileceğini göstermektedir.

Key Words: Gereksiz testler, serbest PSA, laboratuvar maliyetleri, preanalitik faz.

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Introduction

Laboratory tests, which have become an important tool in diagnosis are an integral part of modern medicine and constitute a significant part of hospital expenditure. In recent years, the use of laboratory tests has been increasing worldwide. One of the most important contributors to this increase is unnecessary tests [1-6]. Unnecessarily requested tests were reported as 2.1% to 41% for commonly requested biochemical tests in the literature [2, 7]. Unnecessary tests trigger an unnecessary test request cascade and patient care is negatively affected. In addition, it causes total cost and labour increase in laboratories. For these reasons, the reduction of unnecessary laboratory tests has become even more important in recent years [8-11].

Prostate cancer is the second most common type of cancer diagnosed in men. It is estimated that approximately 1.1 million people will be diagnosed with prostate cancer worldwide in a year [12]. However, the cost-effectiveness of prostate cancer screening is still controversial [13]. Prostate specific antigen (PSA) is an organ-specific marker and increases in prostate hypertrophy, prostatitis and other non-malignant conditions. Free PSA (fPSA)/total PSA (tPSA) ratio is used to distinguish benign prostatic hypertrophy from prostate cancer. Prostate cancer was detected in 56% of patients with fPSA/tPSA <0.10 while in 8% of patients with fPSA/tPSA >0.25 [14, 15]. According to the guidelines of the European Association of Urology (EAU), European Society for Radiotherapy&Oncology (ESTRO) and International Society of Geriatric Oncology (SIOG), the use of fPSA/tPSA ratio is considered clinically insignificant in patients with a tPSA level >10 ng/mL or <4 ng/mL or patients followed up with prostate cancer diagnosis [16].

In this study, we aimed to determine the unnecessary fPSA test requests according to EAU-ESTRO-SIOG guidelines and to evaluate the effectiveness of the information message we added to the hospital information system for unnecessary test requests.

Materials and methods

There is no restriction on fPSA test order in our hospital. For the physicians who ordered the fPSA test, an information note was added to test order page in the hospital information system in 31 June 2017 according to the guidelines and to order fPSA test it has been mandatory to confirm that the information note is read. fPSA and tPSA test results were obtained retrospectively from laboratory information system. Free PSA and tPSA requested in outpatient clinics and inpatient clinics were included in the study. Prostate cancer was accepted as the exclusion criteria. fPSA tests which was requested unnecessarily were evaluated during six-month period before (January 1-June 30, 2017) and after (July 1-December 31, 2017) adding the information message. Uncertainty of tPSA value was calculated according to Nordtest technical report 537 guideline. Uncertainty was calculated using external quality control data obtained from the external quality assurance services (EQAS) program that we are involved in and internal quality control data (PreciControl Tumor Marker 1 and PreciControl Tumor Marker 2).

Standard deviation (SD) and coefficient of variation (CV) values were calculated for internal quality controls (CV%=(standard deviation×100)/laboratory mean (internal quality control)). Intra-laboratory reproducibility (uRW) was calculated using the formula “uRW=√[CV1 (internal quality control level 1)²+CV2 (internal quality control level 2)²]/2”. External quality control bias results were used for calculation of root mean squares of biases (RMSbias). RMSbias was calculated by the formula “RMSbias=√∑bias (external quality control)²/Number of external quality control”. The uncertainty of nominal values (uCref) was calculated (uCref=Reproducibility between laboratories (sR)/√Average number of laboratories using the same method and analyser). Standard uncertainty (ubias) was calculated (ubias=√RMSbias²+uCref²). Uncertainty was expressed as an extended uncertainty value expressed at a confidence level of about 95% using the coverage factor k=1.96. Combined standard uncertainty value (uc) was calculated by the formula “ uc=√uRW²+ubias²” and the expanded uncertainty value (U) was

calculated by the formula "U=1.96*u" [17]. fPSA tests which was requested unnecessarily were evaluated in the six months period before and after adding the information note. tPSA test uncertainty was calculated according to Eurachem/CITAC guideline [17]. Uncertainty was calculated using internal and external quality control data (Level 1 and Level 2). The internal quality control uncertainty value of tPSA tests was 4.25% and external quality control uncertainty value was 6.47%. Measurement uncertainty (95% confidence interval) for tPSA was calculated as ±15.49% in our laboratory.

The fPSA tests should be requested in patients with tPSA levels >4 and <10 ng/mL according to EAPS-ESTRO-SIOG guideline [16]. fPSA tests ordered unnecessarily was evaluated by taking into account the uncertainty value. The limit values (4 and 10 ng/mL) were expanded according to the calculated uncertainty. Therefore, the fPSA tests ordered in patients with tPSA levels <3.38 and >11.54 ng/mL were considered unnecessary. In addition, anamnesis notes of patients with fPSA test requested without tPSA were retrospectively evaluated in hospital information system. According to the anamnesis notes, if the patient did not have a tPSA test previously performed in another laboratory, the requested fPSA tests in patients without tPSA test in our laboratory was evaluated as unnecessary.

Descriptive statistics and chi-square analysis were done using SPSS 17.0 (SPSS Inc., Chicago, IL, USA). The obtained data were expressed as number and percentage. The *p* value below 0.05 was considered significant.

Results

The internal and external quality control uncertainty values of tPSA test were calculated as 4.25% and 6.47% respectively. Measurement uncertainty (95% confidence interval) for tPSA was calculated as ±15.49% in our laboratory.

The median (min - max) age of the patients included in the study was 51 (37-58) years. The total number of tPSA test in the six-month period before and after adding the information note were 510 and 426, respectively. Unnecessary fPSA tests of six months before and after the addition of information note are shown in Table 1.

fPSA tests which were ordered unnecessarily decreased in the six-month period after the addition of information note significantly ($p<0.05$). With the addition of an information note, the rate of unnecessary fPSA test decreased from 27.6% to 7.35%. The departments that ordered tPSA and fPSA tests in this period were urology outpatient, internal medicine outpatient, cardiology outpatient, general surgery outpatient. The number and percentages of unnecessary fPSA test and the unnecessary fPSA/all fPSA test were shown according to departments in the six-month period before and after the addition of information note to hospital information system (Table 2).

Table 1. The percentage and numbers of unnecessary fPSA tests which was requested in periods before and after informational note.

	Addition of an informational note about fPSA			
	Before (6 month period)		**After (6 month period)**	
Unnecessary fPSA Test Requests	n	(%)	n	(%)
The number of fPSA test requests in patients with tPSA level <4 ng/mL	82	(84.5)	12	(40)
The number of fPSA test requests in patients with tPSA level >10 ng/mL	8	(8.25)	18	(60)
The number of fPSA test requested without tPSA	7	(7.22)	0	(0)
TOTAL	97	(100)	30	(100)

Table 2. The percentage and numbers of unnecessary fPSA tests and unnecessary fPSA/all fPSA test rates according to clinics in periods before and after informational note.

	Addition of an informational message about fPSA									
	Before (6 month period)					After (6 month period)				
	All fPSA		Unnecessary fPSA		Unnecessary fPSA/ All fPSA	All fPSA		Unnecessary fPSA		Unnecessary fPSA/ All fPSA
CLINICS	n	%	n	%	%	n	%	n	%	(%)
Urology outpatient	316	89.8	65	67.0	20.6	348	85.3	18	60	5.17
Internal medicine outpatient	23	6.53	21	21.7	91.3	30	7.35	7	23.3	23.3
Cardiology outpatient	9	2.56	7	7.22	77.8	30	7.35	5	16.7	16.7
General surgery outpatient	4	1.14	4	4.12	100	0	0	0	0	0
TOTAL	352	100	97	100		408	100	30	(100)	

Discussion

In this study, we determined unnecessarily ordered fPSA tests according to the EAU-ESTRO-SIOG guideline and evaluated the effectiveness of preventive intervention. Our results indicate that, 27.6% of the fPSA tests performed in our laboratory in the six-month period before adding the information note were unnecessary. The number of fPSA tests requests was the most in the urology outpatient clinic and the least in general surgery outpatient clinic. The ratio of unnecessary fPSA test requests to all of the requested fPSA tests was the least in the urology clinic. In the six-month period before the addition of information note, all of the fPSA tests ordered in general surgery outpatient clinics were unnecessary.

Unnecessary test requests are a significant part of the increasing laboratory workload in recent years. Oliveira et al. [2] reported that the unnecessary test rate was 41%. Bridges at al. [10] found that 7.7% of tests were ordered unnecessarily in the hospitalized patients. Test requesting behaviours of clinicians are affected by many factors such as experience, perceived medical and legal risks, patient-related factors such as anxiety, hospital processes and cultural beliefs. Defensive habits, inexperience, inadequate implementation of protocols and guidelines, lack of awareness about the cost of health care and health spending that support more testing further increase the number of unnecessary test requests [18-20]. According to Australian data, 25% to 75% of the tests are requested without evidence and expert opinion and most of the reasons for requesting a test do not meet the guideline recommendations [21, 22]. The use of algorithms and guidelines plays an important role in correction of the overuse/inappropriate of tests [23]. In the study of Sinitsky et al., implementing blood test request form was increased the awareness in the process of requesting test and the number of inappropriate liver function tests decreased in the paediatric intensive care [24]. In another study, after the audit and feedback intervention, the unnecessary test request rate decreased [18]. We have also added an informational note to the hospital information system, which contains guidance on fPSA testing as a preventive intervention against unnecessary fPSA test requesting. The number of unnecessary fPSA tests in the next six months after information note decreased significantly compared to the previous six-month period. The fPSA test was not ordered without the tPSA test in six-month period after the information note. The fPSA tests were ordered only from cardiology, internal medicine and urology outpatient clinics. Moreover, the number of fPSA tests which were ordered unnecessarily decreased significantly in these clinics. Measurement uncertainty represents expected variability in a laboratory result. We have taken into account the uncertainty values for the cut-off values that

we use to determine unnecessary fPSA tests. Therefore, the cut-off values were expanded according to the calculated uncertainty value.

The data of our study showed that most of the fPSA tests performed in our hospital were unnecessary. The unnecessary fPSA test requests significantly decreased with the addition of a simple information note to the test request screen in the hospital information system. The results of our study show that it is useful to remind guide suggestions and protocols with simple information messages when ordering tests to reduce unnecessary labor and costs.

Conflict of Interest: No conflict of interest was declared by the authors.

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