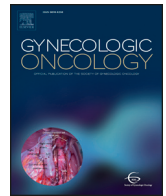




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Prospective screening with the validated Opioid Risk Tool demonstrates gynecologic oncology patients are at low risk for opioid misuse

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HIGHLIGHTS

- The Opioid Risk Tool was an acceptable and feasible screen for opioid misuse risk
- 87% of gynecologic cancer patients screen as low-risk for opioid misuse
- 19% of cervical cancer vs. 2% of non-cervical cancer patients screened as high-risk

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ABSTRACT

Objective. To characterize risk for opioid misuse among gynecologic oncology patients.

Methods. The Opioid Risk Tool (ORT), a validated screen for opioid misuse risk, was administered to a convenience sample of patients with gynecologic cancer receiving opioid prescriptions in gynecologic oncology or palliative care clinics from January 2012–June 2016. Demographic and clinical information was abstracted on chart review. The primary outcome was ORT risk level (low vs. moderate or high). Chi-square tests were performed for categorical variables.

Results. A total of 118 women were screened. Most women were Caucasian (79%) with a median age of 57 years. Ovarian cancer patients comprised 46% of the cohort with fewer endometrial (25%), cervical (23%), vulvar (4%), and vaginal (2%) cancer patients. The median ORT score was 1.0 (range, 0–10) out of a possible 26. Overall, 87% of patients were categorized as low-risk for opioid misuse, 7% as moderate-risk, and 6% as high-risk. Patients who were at moderate or high-risk of opioid misuse were significantly younger (47 vs. 58 years, $p = 0.02$), more likely to have cervical cancer ($p = 0.02$), be smokers ($p = 0.01$) and be uninsured or on Medicare ($p = 0.03$).

Conclusions. Most gynecologic oncology patients in our cohort were low-risk for opioid misuse (87%). Cervical cancer patients were more likely to be moderate to high-risk for misuse. Future screening efforts for opioid misuse may have the highest utility in this subset of patients.

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1. Background

Opioid misuse has been characterized as a public health crisis. Opioid misuse is defined as any use of the drug outside the manner and intent for which it was prescribed. Mortality rates from opioid misuse continue to rise, with over 33,000 opioid overdose deaths in 2015 [1]. Approximately half of these were attributed to prescription drugs and

the number of prescriptions for opioids has been increasing over the past five years [1,2]. Given this climate, there have been multiple restrictions on opioid prescribing enacted and proposed in recent years [3].

Cancer patients comprise a unique population. Opioids are a key component of the management of cancer pain and have been designated as first line therapy for moderate and severe pain by the World Health Organization and the National Comprehensive Cancer Network (NCCN) [4,5]. It is well documented that initiation of opioid treatment often begins too late in the course of end of life cancer care and many patients' cancer pain goes undertreated [6]. New restrictions on opioid prescribing could compound this problem [6,7].

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The American Society of Clinical Oncology recently published a statement recommending that cancer patients remain exempt from the majority of opioid legislation [8]. While it is important to protect access to opioids in this population, there is need for an approach that balances the risks and benefits of opioid prescribing. Risk factors for opioid misuse, such as young age, substance misuse, and psychologic disease have been identified in the chronic pain population [9]. These risk factors have been used to generate validated screening tools for opioid misuse [10,11]. The NCCN guidelines for management of adult cancer pain include recommendations for minimizing risk of opioid misuse. These guidelines support the use of screening tools for risk assessment of cancer patients prior to providing opioid prescriptions [4].

Small retrospective studies have examined risk for opioid misuse specifically in cancer populations [12,13]. Similar risk factors have been described in the cancer population and roughly equivalent rates of being classified as high-risk for opioid misuse have been described for cancer and non-cancer patients [12,13,14]. Opioid misuse risk has not been characterized in gynecologic cancer patients, who are known to have higher pain burdens and opioid requirements compared with other solid tumor patients [15,16].

The primary objective of this study was to use data from a validated screening tool to characterize risk for opioid misuse in a gynecologic oncology population. A secondary objective was to identify risk factors associated with moderate or high-risk for misuse.

2. Methods

A prospective single institution study was conducted with a convenience sample of patients with a diagnosis of any gynecologic malignancy seen in the palliative care or gynecologic oncology clinics from January 2012–June 2016. All patients presenting with either an existing active opioid prescription or those receiving a new prescription were included in the study. Patients were verbally consented and the Opioid Risk Tool (ORT) was administered to enrolled subjects during their clinic visit. The University of Virginia Health Sciences Institutional Review Board approved this study.

The ORT was developed and validated in a chronic pain population and is a 5-item screening tool using age, family and personal history of drug or alcohol misuse, personal history of sexual abuse, and psychologic disease to categorize patients into low, moderate, or high-risk for opioid misuse. (Fig. 1) The individual items on the risk tool are assigned point values and summed for a total score with a maximum value of 26. Tobacco use is not a component of the ORT. The ORT has been

used in both cancer and non-cancer patients [11,12,17,18,19]. Its use as a screening tool in gynecologic cancer patients has been supported by the Society for Gynecologic Oncology (SGO) [20].

The ORT was developed specifically to assess likelihood for aberrant behaviors related to opioid use. This was used as a proxy for opioid misuse. In the initial validation study, the components of the tool were given weighted points based on literature estimates of the most significant risk factors for misuse. Low-risk patients were defined by the authors as those who were unlikely to abuse opioids, high-risk patients as those likely to abuse opioids and moderate-risk patients as equally likely to abuse or not abuse opioids. Patients were screened at initial visit to a pain clinic and followed for 12 months to determine whether they displayed any aberrant behaviors, which was then used to validate the ORT score categories. Aberrant behaviors were broad, ranging from cancelling a clinic visit, to requesting early refills or failing a urine drug screen. This validation study demonstrated a c-statistic of 0.85, suggesting an excellent discriminatory ability for predicting someone who is likely to display an aberrant behavior [11].

In this study, the Opioid Risk Tool was administered by a gynecologic oncology provider (in most cases a gynecologic oncology fellow) or a palliative care attending physician. The tool and its results were placed in the electronic medical record as part of the patient's progress note for that particular visit, as is currently the practice in the palliative care outpatient clinic for all patients using opioid medications.

The primary outcome of the study was categorization of subjects into low, moderate, or high-risk for opioid misuse. A score of 0–3 denoted low-risk patients, 4–7 moderate-risk, and ≥ 8 determined patients at highest risk. Given the low number of patients who screened as high-risk, we chose to group moderate and high-risk patients and compare this group to patients who screened as low-risk. Demographic and clinical characteristics were retrospectively abstracted from review of the electronic medical record. Factors associated with screening either moderate to high-risk were analyzed using Wilcoxon rank sum for continuous variables and chi-square tests for categorical variables.

3. Results

One hundred and eighteen patients with gynecologic cancer were screened with the ORT. All patients who were approached agreed to participate. The screening itself added <2 min to the patient encounter. We did not experience any patient complaints regarding the tool or objections to being screened.

Most women, 64%, were identified through the palliative care clinic, with 36% screened in the gynecologic oncology clinic. The majority of subjects were Caucasian (79%) with a median age of 57 years. Insurance status was fairly evenly divided with 39% having private insurance, 37% were either uninsured or covered by Medicaid, and 24% had Medicare (Table 1). Ovarian cancer patients comprised the majority of patients (46%) with fewer endometrial (25%), cervical (23%), vulvar (4%), and vaginal (2%) cancer patients.

The median ORT score was 1.0 (range, 0–10). Overall, 87% of women screened as low-risk, 7% moderate-risk, and 6% high-risk for opioid misuse. Patients who were at moderate/high risk of opioid misuse were significantly younger (median age 47 vs. 58 years, $p = 0.02$) and also less likely to have private insurance ($p = 0.03$). Cervical cancer patients were significantly more likely than non-cervical cancer patients to screen as moderate to high-risk for opioid misuse. Nineteen percent of cervical cancer patients were high-risk and 7% were moderate-risk compared to 2% high-risk and 7% moderate-risk for non-cervical cancer patients ($p = 0.02$) (Fig. 2). Current or former smokers were also more likely to screen as moderate to high-risk ($p = 0.01$). Race did not significantly influence ORT score ($p = 0.52$). There was also no difference in risk by whether women were screened in the palliative care versus gynecologic oncology clinic ($p = 0.39$).

Of the 15 patients who screened either moderate or high-risk for opioid misuse, 80% (12/15) had a personal history of substance misuse

CONDITION	POINTS
Family History of Substance Abuse	
Alcohol	1
Illegal drugs	2
Prescription Drugs	4
Personal History of Substance Abuse	
Alcohol	3
Illegal drugs	4
Prescription Drugs	5
Age between 16 – 45 years	1
History of preadolescent sexual abuse	3
Psychological Disease	
ADD, OCD, bipolar, schizophrenia	2
Depression, Anxiety	1

Fig. 1. Opioid Risk Tool. Total points are added; low risk ≤ 3 , moderate risk = 4–6, high risk ≥ 7 .

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