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Analyzing the "CareGap": Assessing Gaps in Adherence to Clinical Guidelines in Adult Soft Tissue Sarcoma

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Abstract. Clinical decision support systems (CDSSs) are gaining popularity as tools that assist physicians in optimizing medical care. These systems typically comply with evidence-based medicine and are designed with input from domain experts. Nonetheless, deviations from CDSS recommendations are abundant across a broad spectrum of disorders, raising the question as to why this phenomenon exists. Here, we analyze this gap in adherence to a clinical guidelines-based CDSS by examining the physician treatment decisions for 1329 adult soft tissue sarcoma patients in northern Italy using patient-specific parameters. Dubbing this analysis "CareGap", we find that deviations correlate strongly with certain disease features such as local versus metastatic clinical presentation. We also notice that deviations from the guideline-based CDSS suggestions occur more frequently for patients with shorter survival time. Such observations can direct physicians' attention to distinct patient cohorts that are prone to higher deviation levels from clinical practice guidelines. This illustrates the value of CareGap analysis in assessing quality of care for subsets of patients within a larger pathology.

Keywords. Clinical decision support, clinical practice guidelines, evidence-based medicine, soft tissue sarcoma, cancer treatment

Introduction

Modern medicine requires that physicians acquire large volumes of medical knowledge in order to optimally treat a diverse set of patients. Indeed, doctors constantly need to track new medical knowledge despite having spent typically over a decade in training. Consequently, clinical decision support systems (CDSSs) have been designed to assist doctors in coping with such vast information. Acting as electronic assistants, CDSSs use patient specific parameters entered by caregivers or retrieved automatically from medical records to provide a care recommendation. In theory, a perfect CDSS should provide the optimal care suggestion given knowledge of all patient features.

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Clinical guidelines-based decision support systems are currently one of the leading forms of CDSSs in medical practices. Such CDSSs are rule-based, meaning there is a well-defined input-output function. This is in contrast to statistical methods, local data-driven methods, or hybrid approaches [1]. As adoption of guidelines-based CDSSs by medical institutions is increasing, it is becoming apparent that caregivers do not fully adhere to clinical practice guidelines in various clinical situations [2], [3]. To further understand these gaps in adherence, we compared physician treatment decisions to the recommendations of their local, guidelines-based CDSS for a large population of adult soft tissue sarcoma (STS) patients in northern Italy. The CDSS was available and used by the physicians throughout the duration of the study. By evaluating the physician prescriptions rather than the actual treatments patients received, we were able to filter out noise related to compliance issues. We call this type of analysis "CareGap".

Sarcomas are a rare form of cancer that arises from cells of mesenchymal origin. Comprising around 1% of all cancers, sarcomas are characterized by their diverse histotypes and primary tumor origins [4], [5]. Adult STS accounts for a large proportion of all sarcomas and can present in most body parts including limbs, torso, and retroperitoneum. Tissue origins of STS include cartilage, bone, muscle, fat, and connective tissue among others. The five year survival rates for adult STS are on the order of 60-80% and are influenced by tumor grade, size, location (deep or superficial), and by the presence of metastases [4]. Unfortunately, due to the rareness of STS along with its heterogeneity, adherence to clinical practice guidelines can be rather low, with studies having shown 32% [6] and 54% adherence levels [7].

In this study we performed CareGap analysis focusing on patient-specific characteristics that correlate with adherence levels to the clinical practice guidelines written by the sarcoma experts at Fondazione IRCCS Istituto Nazionale dei Tumori (INT). We identified certain disease parameters that are strongly correlated with adherence levels and other that are not. We also observed a relationship between adherence levels and survival times. This information may be used to improve medical care and documentation by isolating specific clinical statuses that require increased physician attention or corrections to the CDSS and medical record system.

1. Methods and Patients

1.1. Setting and patient data

The present study encompasses a subset of 1329 STS patients treated by INT from November 2006 to July 2012 (Table 1). INT is a specialized cancer medical center within the Lombardy region of Italy, and contains a sarcoma specialty center which treats hundreds of sarcoma patients per year. The patients in this report were between 18yr and 100yr old (median 57yr, 28yr-80yr 5-95% interval). All patients were inpatients for at least a certain fraction of the treatment course. We did not include patients that were treated solely as outpatients, nor did we include patients that belonged to certain rare clinical status groups that had very few patients.

Table 1. Patient characteristics

Feature	Value
Number of Patients	1329
Gender	
Male	715
Female	614
Duration	Nov. 2006 – July 2012
Age Range	18-100 (median 57)

1.2. Description of clinical presentations, treatment programs, and guidelines at INT

In this study, we define a treatment program as a set of medical procedures prescribed for a particular patient during a single decision point. We define the decision point as the point in time in which the treatment program was agreed upon. For STS patients, this can include surgery, radiation, chemotherapy, etc. As expected, most patients had one treatment program prescribed (n= 1120, 84%), with a few having two or more treatment programs (n = 209, 16%). Patients with multiple treatment programs often had a major change in clinical status. Overall, there were 1595 treatment programs prescribed (Table 2).

Table 2: Clinical presentation features of all treatment programs (n=1595)

Location	n	**Grade**	n	**Tumor size**	n	**Tumor depth**	n	**Progression**	n
Limb or torso	1079	High	630	>5cm	434	Deep	517	Local	1226
Retroperitoneum	270	Low	546	<=5cm	105	Superficial	562	Metastatic	246
Not specified	246	Not specified	419	Not specified	1056	Not specified	516	Recurrent	223

We define a guideline recommendation as a unique pair of a clinical presentation and treatment program that is recommended by INT's clinical practice guidelines (defined in ROL - Rete Oncologica Lombarda – Lombardy Oncology Network), with the guidelines being based upon western medical practices for STS. A clinical presentation in INT consists of multiple clinical features such as tumor size, tumor grade, and tumor location. The specific histotype was not used in clinical presentations descriptions. An example of an individual INT guideline recommendation pairs the clinical presentation "Local, high grade, >5cm size tumor located deep (not superficial) in one of the limbs or trunk (not retroperitoneum)" with the treatment program "Wide excision surgery and adjuvant radiotherapy pre- or post- operation". The data in this study encompasses 31 clinical presentations, with 191 possible treatment programs and 344 guideline recommendations in INT's clinical practice guidelines.

1.3. Classifying guideline adherence

Adherence analysis in our study was considered only with respect to the medical decision itself regarding what treatments to administer and did not consider the actual treatments that patients received. Thus, the results were not affected by deviation noise that originated from compliance related issues. We did not assess accuracy of diagnosis, i.e. the accuracy of selecting a patient's correct clinical presentation.

For each clinical presentation, the physician was required to select one of the CDSS recommended treatment programs or to select "Other". If the physician selected one of the CDSS recommendations, the treatment program was considered to adhere with INT's clinical practice guidelines. However, if the physician selected "Other", the medical decision was defined as a deviation. Of the 1595 treatment programs, a small fraction was not classified as either deviation or adherence (6%, n=102) primarily due to technical issues or inaccurate use of the electronic medical record system. The CDSS was active and in use by physicians throughout the entire length of the study.

2. Results

Our goal in this CareGap analysis study was to find patient-specific clinical features that correlate with low adherence to clinical practice guidelines in adult STS patients. We first asked whether specific patient features influence deviation levels. Looking at tumor grade, size, disease progression, and tumor depth, we observed that deviation levels were significantly higher for high grade tumors than low grade tumors (χ^2=43.6, p<0.0001) (Figure 1). Surprisingly, deviation levels in tumors specified as high grade (19%) were still lower than the total average of 24% for all treatment program decision points. The most dramatic finding was the extent to which metastatic presentations had substantially higher deviation levels (χ^2=259, p<0.0001), corresponding to a 4.9-fold increase compared to local presentations. No effect on adherence levels was found with respect to tumor depth (superficial vs. deep) or size (greater than or less than 5cm). The deviation level for recurrent disease (26%) was only slightly higher than the total STS average of 24%. Additionally, we did not find gender effects (male deviation levels: 24%, female deviation levels: 23%) or age related effects (data not shown).

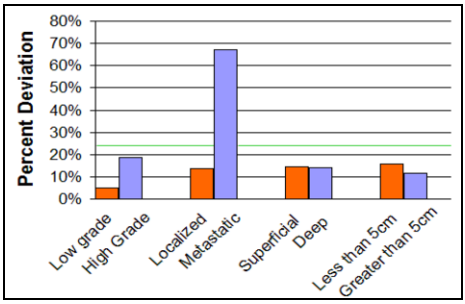

Figure 1. Correlation between disease parameters and guideline adherence for all treatment programs. n values are in table 2. The green line (at 24%) indicates the average for all treatment programs (n = 1595).

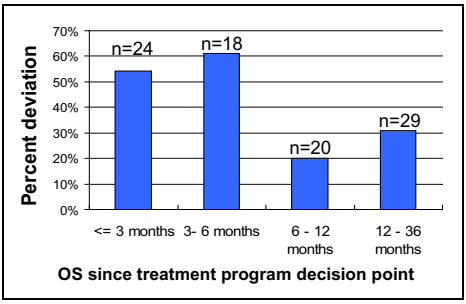

Figure 2. Correlation between adherence to CDSS recommendations and overall survival (OS) among treatment programs in which patients did not survive (n= 91). We do not have data beyond 36 months for deceased patients.

We next evaluated whether survival rates are correlated with adherence levels. Selecting all treatment programs (n=91) in which we knew the patients (n=70) had perished, we assessed the correlation between survival time from the medical decision point and deviation levels from INT's guidelines. Indeed, we observed markedly higher deviation levels for treatment programs with shorter survival durations (Figure 2).

We hypothesized that the latter finding is perhaps related to the earlier observation regarding metastatic and local presentations. In line with the above, we found higher levels of metastasis (71.4% vs. 24.5%) and lower levels of local disease (28.6% vs. 75.5%) in treatment programs with shorter survival times (<=6 months, n=42) compared to longer survival times (>6 months, n=49).

3. Discussion

The level of adherence to guideline recommendations in our study was 70%, which is significantly higher than the two previous sarcoma studies which observed 32% [6] and 54% [7] adherence levels. This can be explained by multiple factors. Methodologically,

we assessed adherence to guidelines based on the physician prescription at the decision point regardless of what actual treatments a patient underwent. This is in contrast to the previous two studies which quantified adherence rates according to the actual treatments that were given to patients. In addition, the previous studies looked at adherence for the whole course of treatment whereas our treatment programs mostly do not include diagnostic tests and follow-up. It is also possible that those studies were performed in the absence of a CDSS system which may help increase adherence as in INT. Finally, adherence may improve over time and can differ between medical centers.

A central theme that rises from our study is that poorer outcome or advanced disease is associated with lower adherence. This is likely a function of the advantages of following clinical practice guidelines often being less substantial in advanced stages. Given the above, it is surprising that tumor size or depth had minimal effect on adherence as larger or deeper tumors are typically associated with poorer outcome [4].

Our present study, while containing a large patient population, is not fully absent of biases. Based on discussions with INT physicians, it is likely that a fraction of the deviations may have resulted from technical issues such as incorrect use of the medical record system. In addition, the exclusion of people treated solely as outpatients and the fact that we omitted a small subset of uncommon adult STS presentations may confer a bias to our patient population. However, these should not have major implications since the study encompassed most of the adult STS patients treated by INT.

CareGap analysis identified specific patient cohorts that were subject to lower adherence to INT's clinical practice guidelines. Such information can subsequently be utilized to optimize documentation, CDSS quality, and medical care. If the deviations arise from technical issues, improving the electronic medical record system may facilitate better treatment documentation. Likewise, a deviation from recommendations may in some instances not be a deviation from best medical practice if the CDSS is not sufficiently comprehensive and updated. Most importantly, low adherence to CDSS recommendations may in certain occasions indicate less than optimal care. Accordingly, CareGap-derived insights may be used to direct caregiver attention towards patients at higher risk of receiving sub-optimal treatment. Future research will attempt to depict the origins of deviations, particularly if they are of technical or medical nature.

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