Implementing clinical practice guidelines: time to assess it

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WHY AND WHAT WAS DONE

ESMO clinical practice guidelines (CPGs) have been developed to provide recommendations for the standard of care according to the highest quality evidence-based data (EBD). European Society for Medical Oncology (ESMO) is also conducting consensus conference (CC) activities to provide answers to crucial questions of clinical relevance, which are then formulated as recommendations.

To be successful, a CPG has to be implemented in daily practice, a multistep process which can be affected by CPG features (complexity, poor access), external factors (social norms, health carers workload, local and national guidelines) and physician personal factors (knowledge and attitudes), but mostly relies on dissemination and physician awareness.1 2

Compliance of physicians with national and/or international guidelines has emerged as an important criterium to assess quality of care. Studies to evaluate the compliance with international guidelines, like National Comprehensive Cancer Network (NCCN), have been performed in patients with breast cancer and in elderly patients with stage III colon cancer3 4 by auditing patients’ medical records.

In 2014, the three main European societies active in gynaecological oncology (ESMO, European Society of Gynaecological Oncology (ESGO), European Society for Radiotherapy and Oncology (ESTRO)) performed a CC in endometrial cancer (EC), the most common gynaecological cancer in developed countries, for the treatment of which a multidisciplinary approach is needed.5 To evaluate the clinical implementation of the recommendations 5 years after the endometrial CC, the three societies conducted a survey, the results of which were reported at ESMO 2020.6

HOW WAS IT DONE

The survey was based on three clinical cases, one by each society. Each case consisted of five questions, each with five possible answers, but only one correct according to CC recommendations and adequate for the specific clinical situation.

The selected topics were the management of early stage endometrioid EC, of high-grade serous histotype and of poorly differentiated stage IIIC EC.

The survey was sent by each society to the members specialised in gynaecological cancers for about a total of 5000 contacts. The answers were collected via Survey Monkey platform in the ESMO website survey dedicated page.

The heterogeneity (H) of answers among the three societies was quantified with I² statistics (ref: http://handbook.cochrane.org/chapter_9/9_5_2_identifying_and_measuring_heterogeneity.htm).

Values of I² >50% represented substantial H.

As indicator of clinical implementation, the percentage (%) of correct answer was adopted with a 70% cut-off value, as it is done with Delphi method for consensus statement in case of a single response.7 8

WHICH WERE THE RESULTS

The survey was kept open from July 2019 to October 2019 and 586 members (of whom 54% from ESGO, 30% from ESMO and 16% from ESTRO) replied.

Overall, >50% of the responders were working in University Hospital or Academic Institutions and 20% in General Hospitals, around 30% were <40 year old, 49% were women and 51% men, 69% of ESGO members were gynaecological oncologists, 74% of ESMO medical oncologists and 86% of ESTRO radiation oncologists specialised in the treatment of gynaecological cancers.
The first case discussed the management of a premenopausal woman with an early stage grade 2 endometrioid cancer, treated with complete surgery followed by adjuvant therapy.

For this clinical situation, the CC recommendations indicated two acceptable options (brachytherapy or no further treatment) according to patient’s age and daily practice because of the lack of EBD. Overall, for each society, the mean % of correct answers was low, from 23% to 60% for ESMO, from 23% to 82% for ESGO and from 35% to 85% for ESTRO (table 1).

The second case was that of a patient with a ‘high-risk’ rare serous histotype, treated with surgery and adjuvant treatment, who presented an isolated pelvic recurrence.

Again, the mean % of ‘correct’ answers was very low, ranging from 17% to 35% for ESMO, from 16% to 49% for ESGO, from 12% to 50% for ESTRO.

The third case discussed the management of a poorly differentiated EC case with lymph node metastases at diagnosis. The main question was on the modalities of the adjuvant therapy, with the possible options of chemotherapy or of chemotherapy in combination with radiotherapy. The highest H was in the preferred sequence of the combined approach and on the modalities of the initial surgery. Overall, the mean % of correct answers ranged from 17% to 44% for ESMO, from 8% to 56% for ESGO, from 19% to 46% for ESTRO (table 1).

The per cent of non-responders increased from the second case up to a maximum of 48% in the third one, thus affecting the value of the results.

Table 1  Heterogeneity and mean % of correct answer in each clinical case

<table>
<thead>
<tr>
<th>Clinical scenario</th>
<th>Case 1 early stage</th>
<th>Case 2 high-grade serous</th>
<th>Case 3 stage III C1</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;50% Heterogeneity</td>
<td>3/5 questions</td>
<td>3/5 questions</td>
<td>4/5 questions</td>
</tr>
<tr>
<td>Overall mean % correct answers (range)</td>
<td>26%–75%</td>
<td>16%–44%</td>
<td>14%–51%</td>
</tr>
<tr>
<td>ESMO mean % correct answers (range)</td>
<td>23%–60%</td>
<td>17%–38%</td>
<td>17%–44%</td>
</tr>
</tbody>
</table>

WHAT WE LEARNED

Even though EC is the most common gynaecological malignancy in developed countries, EBD on some aspects of clinical management are limited and often daily practice is still based on personal experience and traditional approaches. In addition, EC has for a long time been considered a slowly growing disease, mainly of older women with many comorbidities, usually diagnosed at an early stage, hormone-dependent and well controlled by surgery and pelvic radiotherapy in selected cases, treated by gynaecologists or gynaecological oncologists and radiation oncologists. Trials on adjuvant chemotherapy in high-risk disease and the increased knowledge of the different genomic profiles, resulting into four subgroups with different molecular signatures of prognostic value, have significantly changed the clinical management, introducing targeted treatments and reinforcing the need of a multidisciplinary approach with an essential role for medical oncology.

The previous studies to assess compliance with NCCN guidelines were done by auditing medical records, the results of which were affected by the availability and completeness of the source documents; our approach, based on Q&A on clinical cases, is possibly more correspondent to physician knowledge and local practice.

A limitation of our study is the relatively small, selected sample size studied (586 responders over about 5000 contacted, with >50% responders working in University Hospital or Academic Institutions). Still, the results of this survey are of value because they showed a limited implementation of the recommendations of the CC, regardless of specialty and main topic of the question. In addition, the great H of responses among the three societies might indicate the lack of a multidisciplinary perspective on the clinical management and different interpretations of the published data. Other potential factors for H among the three societies performance could have been the different degrees and type of clinical experience, which is related to previous and ongoing activities, work setting (eg, large specialised centre vs general hospital) and local availability of therapeutic resources.

Possible reasons for the low % of correct responses were the lack of EBD to support a strong recommendation or the lack of a specific recommendation in the CC, the lack of EBD because of the rarity of the disease, the introduction of a new surgical technique like sentinel node biopsy or the availability of new significant clinical results, shortly after the publication of the CC recommendations, as it was the case for the management of stage III C9–11 with changes in clinical practice.

The high per cent of non-responders decreases the value of the results and might indicate a lack of knowledge due to limited experience, lack of time or lack of interest, the last two points suggesting that the survey was felt to be too long, with too many cases and too many questions.

HOW TO MOVE FORWARD

ESMO is greatly committed to make available updated, evidence-based (EB), complete high-quality multidisciplinary CPG and CC recommendations as free accessible tool to improve patients care.

This first ESMO attempt to evaluate the implementation in clinical practice of the CC recommendations on EC was somewhat disappointing because it showed an
overall limited implementation; however, it has been useful to identify pitfalls in the CC recommendations (lack of regular updates, lack of clarity in wording, availability of different options, ambiguous indications, lack of recommendations on some crucial topics). Besides improving the quality of CC recommendations and CPG features, ESMO is also very much committed to expand the guidelines-related activities, in which dissemination and training are a priority, to be further promoted by a direct involvement of the authors, by providing a set of slides for citation at meetings, public presentations and local training; compliance can be then regularly assessed by surveys with case histories with a maximum of four straightforward questions, formulated with a clear wording, specifically referring to CC recommendations or CPG.

Once more, this survey confirmed the value and the need of a multidisciplinary approach in the preparation of the CC recommendations and CPG and in the clinical management of patients with cancer.

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