IGCC

10th INTERNATIONAL GASTRIC CANCER CONGRESS

2013 Verona

June 19 - 22

Tailored and Multidisciplinary Gastric Cancer Treatment

The CHARTER SCALIGERO on GASTRIC CANCER

IGCA

INTERNATIONAL GASTRIC CANCER ASSOCIATION

IRGGC

Italian Research Group for Gastric Cancer

Verona, June the 22th, 2013

Dear Colleague,

It is a great pleasure to introduce You to the **CHARTER SCALIGERO ON GASTRIC CANCER.** For the first time in the history of the International Gastric Cancer Congresses, the Scientific Committee wished to produce a joint document, which meant to be the 10IGCC legacy to the scientific community, when passing the baton to colleagues who will organize the 11IGCC in 2015.

A key point in the CHARTER SCALIGERO is the CONSENSUS CONFERENCE entitled **RATIONALE OF ONCOLOGICAL FOLLOW-UP AFTER GASTRECTOMY FOR CANCER,** which is the product of a long-lasting Delphi exercise, attended by a wide panel of international experts and specialists and concluded in a Consensus Workshop held in Verona during the 10IGCC. The last Congress day, June the 21th, in the presence of the press, the CHARTER has been officially presented, and since that moment it can be undersigned by returning the application form herein enclosed to the organizing secretariat, or by affixing a digital signature in the CHARTER SCALIGERO page of the website www.10igcc.com.

We are thankful in advance for Your priceless cooperation, and looking forward to receiving Your support, we send warmest personal regards,

Sincerely

Web Consensus Conference Co-Chairmen

Domenico D'Ugo
Daniele Marrelli
Yasuhiro Kodera
Gian Luca Baiocchi

President 10th IGCC

Giovanni de Manzoni

Secretary10th IGCC

Franco Roviello

Charter Scaligero Methodology Specialist

Claudio Detogni

Scientific Secretariat

Paolo Morgagni, Daniele Marrelli

10th GASTRIC CANCER CONGRESS

Verona: June 19-22, 2013

THE CHARTER SCALIGERO ON GASTRIC CANCER

The Charter Scaligero on Gastric Cancer was developed by a panel of international experts that, after a long Delphi Technique exercise, finally gathered at a Consensus Conference in Verona (Italy) on June 22, 2013 in the context of the 4 days work (from June 19 to June 22) at the 10th Gastric Cancer Congress venue.

Aim

The aim of the Charter is to lay the foundations for articulating a common universal vision and implementing global standards for contributing to the improvement of effectiveness and efficiency in the struggle against the effects of gastric cancer with the ultimate scope of ameliorating the quality of life of people affected by the disease by strengthening the quality of early detection, treatment and cure and scrupulous follow up with a special attention and commitment to the prevention measures.

The Charter is not intended to lay down new rights with legal value.

The 10th Gastric Cancer Congress participants, in coordination with the International Gastric Cancer Association, with International Institutions and Agencies and with all Stakeholders will be committed to guarantee the implementation and the world-wider diffusion of the Charter.

Disclaimer: The content of this document has been agreed by the institutions and individuals that participated in the Consensus Conference held in Verona on the 19th to 22nd June 2013. Although some changes may be made to this document in terms of formatting end editing, no change can be made to its content as it has been agreed on and endorsed by the institutions and individuals that participated in the Consensus Conference. Furthermore, the list of final founding signatories is still under completion.

PREAMBLE

Gastric cancer, once the second most common cancer in the world, has declined in developed countries over the past 30-40 years, and actually rates as the 4th most commonly occurring cancer after lung, breast and colon-rectum, and the 2nd most common cause of cancer-related death. Nearly one million new cases of gastric cancer are recorded yearly, accounting for about 8% of all cancer cases.

Decreases in gastric cancer rates have been attributed both to dietary changes linked to the widespread implementation of refrigeration (which entailed increased consumption of fresh fruits and vegetables, decreased intake of salt and decreased contamination by carcinogenic compounds arising from the decay of unrefrigerated products) and to a 20 years lasting *Helicobacter pylori* eradication, due to improved sanitation and use of antibiotics; in some countries, screening policies have also contributed to lowering gastric cancer incidence. The above said demonstrates once again how the policies of prevention and health promotion are truly able to have a beneficial impact on the natural history of cancer.

There is a 10-fold variation in the incidence of gastric cancer across the world; age-standardized incidence rates range from about 4-6/100000 person-year in Africa, North America, Western and Northern Europe and Australia, to 10-15/100000 person-year in Southern, Central and Eastern Europe and Southern and Central America, to 30-35/100000 person-year in Eastern Asia. New cases occur twice as often in men as in women.

Gastric cancer is multifactorial, involving both inherited predisposition (some 10% of stomach cancer cases are familial in origin) and environmental factors: diet (a diet rich in pickled vegetables, salted fish, salt, and smoked meats correlates with an increased incidence of gastric cancer), smoking (the risk is increased by approximately 1.5- to 1.6-fold), *Helicobacter pylori* infection (via the pathway of chronic atrophic gastritis, rising by 6-fold the risk), obesity (especially for cardia cancer), previous gastric surgery, pernicious anemia and radiation exposure.

Some countries (i.e. Japan, Chile, Venezuela) have developed a screening program aimed at detect patients with early stage disease. These patients appear to do quite well. Outside screening programs, about one third of gastric cancer patients present with localized disease, one third with regional disease, and the remaining present with distant metastatic disease. While early disease is usually asymptomatic, most symptoms of gastric cancer (vomiting, dysphagia, loss of appetite, melena, hematemesis, and weight loss)

reflect advanced disease. Late complications include peritoneal and pleural effusions, obstruction of the gastric outlet, bleeding, jaundice, cachexia. It is therefore of paramount importance implementing the screening policies, in which the surgeon is rarely involved, in order to reduce the proportion of advanced cancers and consequently the mortality rate, breaking down in addition the economic and social costs related to the treatment of advanced cases.

In recent years, surgery, which was the only treatment for gastric cancer, has been integrated by endoscopic and chemo-radiotherapy treatments. Currently in some patients with early cancers, provided accurate diagnosis and staging are available, endoscopic resections (mucosal and submucosal) are performed, improving the quality of life while maintaining, if applied with the correct indications, the same results. On the other side, in the case of advanced cancer, the possibility of preoperative treatments has opened the way to studies aimed at improving survival when surgery alone would fail. However, surgical treatment remains the mainstay of the therapy. It should guarantee the best quality of digestive tract reconstruction and the correct lymphadenectomy, in order to offer patients the best chance for cure.

The operative mortality rate for patients undergoing curative surgical resection at major academic centers is less than 3%. The recurrence after curative therapy is fairly common and the great majority of cases are not susceptible to cure. For this reason, it appears unproven that offering patients regular instrumental checks makes sense. Overall, the 5-year survival rate for a curative surgical resection ranges from 60-90% for patients with stage I, 30-50% for patients with stage II disease, and 10-25% for patients with stage III disease.

Furthermore, since in all life-threatening diseases patients and their families suffer from understandable psychological weaknesses, that cannot be underestimated by the medical system, following them up may represent a useful way to strengthen their capacity to tackle the disease in which the surgeon may play an active role.

Methodology

1. Appointment of a Restricted Working Group by IGCC Scientific Committee **(*Dec 1st 2012*)**
2. Production of a preliminary document by the Restricted Working Group, enlightening the main relevant data in the literature and the unsolved clinical issues **(*January 20th 2013*)**
3. Restricted Working Group suggestion to the IGCC Scientific Committee of a list of names as invited experts in an "Enlarged Working Group" **(*March 15th 2013*)**
4. Enlarged Working Group members confirmed their participation and acceptance of the rules of the Charted construction **(*April 15th 2013*)**
5. Through the Delphi Method any member of the Enlarged Working Group has blindly reviewed the statements issued by the Restricted Working Group **(*June 4th 2013*).**
6. The final document, reviewed in a final workshop held during the Congress by the representative panel of specialists who participated in the exercise for final formal endorsement **(June the 21st 2013)**, has been presented and displayed for open discussion to all participants during the Congress Consensus Conference; the document was then available for signature for alla the 10ICGG participants, and thereafter worldwide, at website www.10igcc.com **(June the 22nd 2013)**.

THE CHARTER SCALIGERO ON GASTRIC CANCER

WE, Health Professionals,

and the distinguished participants in the Consensus Conference on 'The Charter Scaligero on Gastric Cancer' who undersigned this CHARTER:

- with a view to ensuring to all persons affected and not affected by the disease, irrespective of age, sex, provenience and legal status, the protection of human and fundamental rights and the effective exercise of the right to independence, social inclusion and full participation in the life of the community, with a particular attention to all vulnerable people including elders, women, children, migrants and persons with disability;
- reaffirming the universality, indivisibility, interdependence and interrelatedness of all human rights and fundamental freedoms and the need for persons with disabilities due to diseases to be guaranteed their full enjoyment again without any form of discrimination;
- recognizing that persons with debilitating diseases are involved in stressful experiences therefore care should include whenever needed the best psychological support possible;
- recalling the willingness, commitment and availability of all the personnel of the health care private and public Institutions of being involved and provide her/his contribution in all stages of health promotion, prevention, detection, treatment and cure, and follow up with reference to the disease

Have agreed as follows:

Art. 1 - Scope of the Charter

The aim of this charter is to lay down the foundations for articulating a common universal vision as well as highlighting some relevant aspects of what would be needed to support the best prevention, early detection, treatment and cure, and follow up of the disease.

Art. 2 - WHO Definition of Health

While guaranteeing full endorsement and commitment to the World Health Organization definition of Health as it entered into force on 7 April 1948 "Health is a state of complete Physical, Mental and Social well-being and not merely the absence of disease or infirmity", we hope that Spiritual Health will soon be included.

Art. 3 - Stakeholders and actors involved

Specific needs of the persons affected by the disease and their families should be further understood and addressed. They are themselves a key source of information useful to the health personnel who is involved in providing care and who is committed to alleviating their suffering. Not only surgeons and health personnel but all other stakeholders, including the civil society and individual citizens, Governments, international Agencies, NGOs and other profit and no profit institutions, should be called to bring their contribution.

Art. 4 - Governmental responsibility & Liabilities

It is the responsibility of Governments at all levels to take all the measures necessary to ensure the appropriate provision of facilities and means to sustain the services required to provide care and to avoid any discrimination.

Art. 5 - Cultural respect and more vulnerable groups

Particular attention must be paid to persons more vulnerable to guarantee equal care, such as elderly people, women, children, disabled persons, minorities including migrants considering all logistic condition and cultural frameworks.

Diversity among persons should be acknowledged and needs to be accommodated in planning, mitigation and recovery strategies.

Art. 6- Research, Techniques & Technology development

The potential of new technologies should be fully implemented. The diffusion of new technologies and techniques should respect the concept of appropriate techniques and therefore not be threatened by problems of costs, availability, difficulties in their use.

Of paramount importance is to conduct research and adopt an evidence based approach that, through a continuous process of monitoring, evaluating, exchanging and sharing of experiences, shall bring to the adoption of shared good practices. The concept and identification of good practices are tightly linked with social, economical and technological

changes. Effective and efficient good-practice sharing systems should be promoted. The success of this process lays in an approach that keeps in high consideration the substantial differences in the economical, social, cultural and environmental situations of different States, contexts and realities.

All experiences done in developed countries as well as in less developed countries should be exchanged by fostering international health cooperation and mutual support should be encouraged among them.

Art. 7 - Information to the public, raising awareness and the role of arts and cultures

a. The Governments and all stakeholders are urged to adopt all the effective and appropriate measures to raise awareness throughout society, including school and family, regarding the risk factors of the disease.

b. Every individual has the right to be provided with information regarding available services, facilities, materials, infrastructures, technology and appliance norms and injunction to use them, adoptable rules of conduct and every other type of information, such as commonly recognized information numbers, considered useful for decreasing the risk of developing the disease and, eventually, for receiving proper cures and treatments.

c. Information should be correct and easily understandable, accessible by all and appropriate to meet the different needs of persons at risk or with the disease.

Information should also be positive, encouraging, helpful and financially affordable by everybody.

The effectiveness of information should be monitored through identifiable and measurable indicators.

All sectors have the responsibility to contribute to having well-informed and safety-oriented citizens, members, employers or readers. The responsibility for information does not lie solely within one sector.

Raising awareness on the issue of the prevention and appropriate care of persons with the disease should be considered a priority.

Special consideration should be assigned to the role of arts and culture which, thanks to their universal language, can reach the wider community.

Art. 8 - Capacity building including Training

All systems involved in the prevention, care and rehabilitation should be properly capacitated. This process should include strengthening of infrastructures, providing adequate equipment, defining effective protocols and reinforcing organization.

All actors involved should be sensitized, informed, trained (including practical exercises and cross-training) and motivated in order to fulfill their responsibilities.

Art. 9 - Dissemination & Exchange of experiences

It is important to promote a constant, permanent and regular collaboration and partnership among stakeholders at local, national and international level. Collection of protocols, technologies, techniques, scientific documents, reports on any action undertaken should be easily shared. Wide dissemination of the outcome of such processes is deemed in this regard necessary. Information is of little value without dissemination.

Art. 10 - International Alliance & Networking

In order to ensure an effective exchange of experiences and knowledge of good practice, stable international networks are needed. International benchmarking is also desired. International networks will be more effective if based on consolidated regional and national networks in each State.

Competent institutions should promote research activities, expert advice, advocacy and information dissemination which are of paramount importance in increasing a correct understanding of the matter at all levels.

Art. 11 - Information and Registration systems: Statistics & Data

All the scientific society and stakeholders involved should strive to make information relevant and comparable. Reliable, comprehensive and regular data collection systems should be established as they are crucial for quantifying the problems, identifying risk factors and monitoring and assessing the effectiveness of interventions on the basis of assessable practices.

It is important to develop scientific methodology to compare different approaches across

different international contexts and across time in the respect of privacy. Governments at all levels are called upon to give their support to the development of these methodologies.

Art. 12 - The role of patients, surgeon and of other medical categories in health promotion and social marketing

Health promotion has been defined by the World Health Organization's (WHO) 2005 Bangkok Charter for Health Promotion in a Globalized World as "the process of enabling people to increase control over their health and its determinants, and thereby improve their health".

Health promotion and social marketing focus on changing behavioral risk factors and their potential integrative nature of the approaches should be reinforced.

Despite medical categories, including surgeons, are recognized having great authority and influence in the public belief, unfortunately they have been scarcely considered and rarely involved in health promotion activities and programs so far.

Studies are encouraged to investigate the role of surgeons, nurses and other medical categories as health promoters and opinion leaders. It is hoped that clinicians and health staff in hospital settings and outside perceive health promotion as part of their role. The System has to accept the role of these Professionals in promoting health; this in comprehensive and integrated manners not only among professionals but also between hospitals and the territory they serve. As there is a growing awareness that patients should play a more active role in their treatment and after care in a continuous process of humanization of health care.

Art. 13 - The role of the "follow up" in the management of Gastric Cancer

The appropriate management of the disease is fundamental not only for improving the patients' quality of life but also in order to decrease unnecessary costs for the health systems. A panel of experts who participated in the 10th IGCC have elaborated a vision and reached a consensus on a number of statements that are intended as a guide of principles that would be of help to better manage the follow up of the disease after surgery. The Institutions and Professionals who endorsed this Charter and the "statements on the follow up" commit themselves to implement methodologies that will be reviewed, on the bases of evidence, in future congresses with the scope to come in the future to common approaches. The statements are attached to this Charter and available to all the scientific community.

Art. 14 - Funding

There is a need to guarantee sufficient funding for research and development, as well as training.

Art. 15 – The way to an epoch-making goal

The 10th ICGC Congress participants consign this Charter to the University of Verona - Upper Gastrointestinal Division Department of Surgery – who will take care of the dissemination of the Document in the next two years and take it to Brazil in 2015 for further revision.

The participants of the consensus conference entrust the Organizers of the 10th IGCC to submit the Charter Scaligero to the major national and international stakeholders for consideration. The Charter is submitted for consideration by civil society, regional, national, European and International Institutions.

The progress of the Charter will be reported at the next 11IGCC, which will be held in San Paolo (Brazil) in 2015.

ANNEX

To the "CHARTER SCALIGERO ON GASTRIC CANCER"

Rationale of oncological follow-up after gastrectomy for cancer

Introduction

At present, there is no incontrovertible evidence about the role of oncological follow-up after radical gastrectomy for cancer; albeit many retrospective series have clearly demonstrated that diagnosis of tumor recurrence in the asymptomatic phase has not resulted in an improvement in survival, compared to late diagnosis which is generally consequent to the appearance of symptoms, the clinical practice guidelines in many high volume centers imply that patients are submitted to scheduled clinical and instrumental checks, with the aim to minimize the nutritional sequelae of gastrectomy and to timely diagnose tumor recurrence.

The rationale for this relies on 3 factors:

1. In the near future, biomedical research will hopefully offer therapeutic weapons for metastatic and/or relapsing patients.
2. Improving the standard of quality in surgical oncology is a process that cannot be separated from a daily evaluation of the results of therapies, by comparing results from different surgical series and different schedules of complementary therapies; such evaluation is made possible only by reliable data on recurrence and survival.
3. For most patients, being subjected to seriated follow-up checks does not represent a source of stress, but this has rather the potential of reassuring them.

On the other hand, it is certainly needed that follow-up schedules are based on a more solid evidence, by identifying tests and examinations with the best reliability and sensitivity, and by limiting them to a period of time when recurrence is likely.

The 10th IGCC Scientific Committee has launched an international, web-based consensus process entitled on the *" oncological follow-up after gastrectomy for cancer".*

Aim

Aim of the Consensus Exercise was to present an ideal prototype of follow-up, after radical gastrectomy for cancer, which is based on shared experiences, taking into account at the same time the need to rationalize the diagnostic course and not to lose the chance to catch a recurrence at its earliest stage.

Other factors to be considered are : - need of reliable data on surgical results; - patients' desire not to be abandoned; - psychological stress induced by unuseful controls; - cost/benefit ratio of instrumental examinations; - side effects of invasive diagnostic procedures; - possibility of causing a premature "diagnosis of death".

Working Questions

1) Should the patients be completely lost after radical surgery and eventual adjuvant chemotherapy?
2) Should follow-up be done exclusively by GP instead of surgeon, oncologist, gastroenterologist?
3) Should follow-up be differentiated on the basis of recurrence risk?
4) Should only clinical checks be done during follow-up?
5) Should advanced imaging techniques be regularly prescribed during follow-up?
6) Should upper GI endoscopy be regularly prescribed during follow-up?
7) After how many years follow-up should be stopped?

Approved Statements

Statement #1

There is no evidence that routine followup after curative treatment of gastric cancer (R0 resection with or without adjuvant therapy) is associated with improved long term survival. However, routine followup should be offered to all patients, for both clinical and nonclinical reasons: oncologic (detection and management of cancer recurrence), gastroenterologic (endoscopic surveillance and management of postgastrectomy symptoms), research (collection of data on treatment toxicity, time to and site of recurrence, survival, and cost benefit analyses), and pastoral (psychological and emotional support). Followup should include lifetime monitoring of the nutritional sequelae of gastrectomy, including, but not limited to, adequate vitamin B12, iron, and calcium replacement.

Statement #2

Followup should be performed by members of the multidisciplinary team who managed the initial diagnosis, staging and treatment, including the gastroenterologist, the surgeon, the medical and radiation oncologists, and the general practitioner.

Statement #3

Followup of patients following curative treatment of gastric cancer should be tailored to the individual patient, to the stage of their disease, and to the treatment options available in the event that recurrence is detected.

Statement #4

Physical examination rarely detects asymptomatic recurrence of gastric cancer. A followup program intended to detect asymptomatic recurrence should be based on cross-sectional imaging. There is no evidence that intensive cross-sectional imaging surveillance of gastric patients is associated with improved long term survival. However, as a matter of clinical care following curative treatment of gastric cancer, it is reasonable to prescribe periodic imaging at a frequency consistent with recurrence risk. The incremental value of screening for elevated biochemical markers in addition to cross-sectional imaging remains undefined.

Statement #5

Upper GI endoscopy may be used to detect local recurrence or metachronous primary gastric cancer. True local recurrence is uncommon, but if present, may be considered for resection with curative intent, especially in patients who initially presented with early stage disease. The cost-benefit ratio of endoscopic surveillance of the anastomosis and/or gastric remnant remains undefined.

Statement #6

Routine screening for asymptomatic recurrence of gastric cancer may be discontinued after five years, as recurrence beyond that interval is very rare.

Restricted Working Group members

1. Baiocchi Gian Luca *(Brescia, Italy)*
2. D'Ugo Domenico *(Roma, Italy)*
3. Kodera Yasuhiro *(Nagoya, Japan)*
4. Marrelli Daniele *(Siena, Italy)*

Enlarged Working Group members

1 Allum William *(London, Uk)*
2 Asoglu Oktar *(Istambul, Turkey)*
3 Berruti Alfredo *(Brescia, Italy)*
4 Cascinu Stefano *(Ancona, Italy)*
5 Chandramohan SM *(Chennai, India)*
6 Coburn Natalie *(Toronto, Canada)*
7 Coit Daniel *(New York, USA)*
8 De Manzoni Giovanni *(Verona, Italy)*
9 Fujitani Kazumasa *(Osaka, Japan)*
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11 Hardwick Richard *(Cambridge, UK)*
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14 Hyung Woo Jin *(Seoul, Korea)*
15 Ito Seiji *(Aichi, Japan)*
16 Jansen Edwin *(Amsterdam, Netherlands)*
17 Karpeh Martin *(New York, USA)*
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20 Kolodziejczyk Piotr *(Krakow, Poland)*
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47 Yoshikawa Takaki *(Yokohama, Japan)*
48 Zaniboni Alberto *(Brescia, Italy)*

Methodology supervision

Detogni Claudio *(Verona, Italy)*

Final Workshop Rapporteur (Friday 21st June 2013)

Stefania Gazzani *(Rovereto, Italy)*

THE CHARTER SCALIGERO ON GASTRIC CANCER

I, the undersigned _____

Affiliation _____

_____

Address _____

_____

Contact details _____

_____

I declare that I endorse the CHARTER SCALIGERO on GASTRIC CANCER in its entirety; I commit myself from now on to spread it in my working environment and beyond and to implement it in my daily clinical practice; with regard to the CHARTER SCALIGERO on GASTRIC CANCER contents, I also engage myself to report every two years the results of my experiences and express my viewpoint, in the ways and in the times that the Promoter Committee will deem appropriate. I am aware that mine and the others' contribution will improve the CHARTER in the future versions.

Signature

a- As an individual _____ *or*

b- On behalf of my Institution _____

Place_____Date_____

To be Hand-delivered or to be sent to:

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