

IMPACT OF NEUTROPENIA IN CHEMOTHERAPY EUROPEAN STUDY GROUP

The mission of the Impact of Neutropenia in Chemotherapy European study group (INC-EU) is to raise awareness and prevent the occurrence of chemotherapy-induced neutropenia (CIN) by assessing the incidence, consequences and patient risk factors and by identifying and developing accurate prediction models for CIN, such that high-risk patients can effectively be targeted for preventative measures.

Welcome to the spring 2005 edition of the INC-EU Insight newsletter. This newsletter communicates the latest news to all healthcare professionals (oncologists, haematologists, nurses, pharmacists, hospital medical directors) involved in the treatment of cancer using cytotoxic chemotherapy. The following articles describe current INC-EU activities, the latest results of the INC-EU retrospective and prospective studies and progress reports from other groups involved in neutropenia and oncology.

We hope you find the articles in the newsletter useful.

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► In this edition ...

- In **An update from the INC-EU** you will find news from the 5th INC-EU meeting, which took place in October 2004, as well as of progress on the 'Prospective Observational European Neutropenia Study'.
- **News from America** reports the latest results from the American Study Group 'Awareness of Neutropenia in Chemotherapy' (ANC).
- **In the literature** highlights a selection of recently published advances in neutropenia and chemotherapy.
- Selected abstracts from the European Society for Medical Oncology (ESMO) 2004 congress are covered in **Update from scientific meetings**. Also included in this section are a review of INC-EU presentations and a list of oncology meetings for 2005.
- **An update from the European Oncology Nursing Group** describes the success of TITAN (Training Initiative in Thrombocytopenia, Anaemia and Neutropenia) pilot projects as well as a recent meeting between the European Oncology Nursing Society (EONS) and INC-EU representative, Ruth Pettengell.
- Finally, contact details of the INC-EU coordinating centre can be found on the last page of this newsletter.

► INC-EU website

You can access more information about the INC-EU by registering on the website at www.inceu.org.

On the website you will find:

- Information on INC-EU goals, objectives and activities;
- Details of INC-EU members;
- Dates of important meetings;
- Useful links to other oncology websites.

► Email contact

If you would like to contribute an article or require further information, we would appreciate hearing from you. Please send an email to info@inceu.org.

An update from the INC-EU

► News from the 5th INC-EU meeting

On Thursday 29 October 2004, the INC-EU met in Vienna to discuss the achievements and future directions of the INC-EU.

Presentations were made on the activities of the INC-EU, the TITAN project from EONS and the Neutropenia Audit Package (NAP). There was also a guest presentation from Prof. Gary Lyman, representing the ANC. Details of his presentation can be found in the 'News from America' section of this newsletter, and details of the TITAN project can be found in the 'Update from the European Oncology Nursing Group' section.



Future progress through communication and collaboration

One of the key outcomes of the meeting was that future progress would be made through enhanced communication and collaboration. In this respect, decisions were made for the INC-EU to:

- form closer links with ANC;
- form closer links with EONS, and particularly the TITAN project;
- share information with centres in countries not involved in the original INC-EU studies, particularly in countries where clear guidelines are not currently in place;
- liaise with centres that are running NAP programmes to allow a comparison of data;
- increase communication of INC-EU activities by re-launching the INC-EU website and distributing the Insight newsletter more widely.

Some of the INC-EU study group meeting participants. From left to right: Matthias Schwenkglenks MA, MPH, PD Dr Christian Jackisch, Dr Ruth Pettengell, Prof. André Bosly, and Dr Manuel Constenla. Matthias Schwenkglenks is Head of Research at the European Centre of Pharmaceutical Medicine (ECPM), based at the University of Basel, Switzerland. He collaborates with the INC-EU to provide expertise on the design of INC-EU studies and statistical analyses of data generated by them.

Note: the next INC-EU study group meeting will take place on Monday 28 February 2005 near Frankfurt, Germany.

► Progress report from the Prospective Observational European Neutropenia Study

Patient recruitment has passed the 50% milestone and continues to increase

On 15 November 2004, recruitment of patients reached the 50% milestone. Since then the number of patients recruited has grown further, to reach 323 out of a target of 450 breast cancer patients and 209 out of a target of 300 lymphoma patients by the end of January 2005. Despite this achievement, the INC-EU and participating centres continue to work hard to keep the momentum high. Non-recruiting centres were contacted to find out if additional assistance was required and posters summarising important study information in local languages were delivered to study sites at the beginning of December 2004 with the aim of increasing awareness of the study.

First presentation of the study at international congress

The methodology and recruitment progress were presented at the 9th International Primary Therapy of Early Breast Cancer conference, St. Gallen, Switzerland in January 2005 (Pettengell *et al.* 2005).

► Successful launch of the NAP

The NAP is a programme that allows clinicians to capture data on the frequency and duration of neutropenia following chemotherapy and compare their own clinical practice with reference data (see Insight issues 2 and 3). The programme has been successfully launched in centres in Poland, Hungary, Slovakia, Sweden and the Czech Republic, and 896 patients were registered on the project by the end of January 2005. Data collection is active and very lively and the analysis of data from completed countries is expected to start soon.

Aims and objectives

The Prospective Observational European Neutropenia Study is designed to better define the relationship between risk factors and neutropenia. The main study objectives are:

- to estimate the incidence of grade 3/4 neutropenia following common myelosuppressive chemotherapy regimens;
- to assess the frequency and severity of febrile neutropenia (FN) and of neutropenia-induced chemotherapy dose delays and dose reductions;
- to identify associations between neutropenia risk factors (e.g. treatment characteristics, comorbidities) and neutropenic event occurrence, and between neutropenic event occurrence and impaired chemotherapy delivery;
- to contribute to the development of a clinically effective risk model, which will identify patients who are at an increased risk of experiencing neutropenia, in order to target prophylactic measures.

News from America ...



Prof. Gary Lyman,
director of the ANC

below 65% was equivalent to not receiving chemotherapy at all. He concluded that the risk of dose reduction leading to death from cancer has to be balanced with the risk of FN, which can also cause death.

Prof. Lyman additionally gave progress reports on the various ANC studies.

The ANC retrospective study

The ANC retrospective study involved a review of randomised trials for breast, lung colon and ovarian cancers between 1990 and 2000. It was found that in general, reporting of many aspects of the treatment, including received dose and neutropenic events, was quite poor. Data relating to breast cancer were published in 2003 (Lyman *et al.* 2003). The lymphoma data were recently published in the same journal (Lyman *et al.* 2004), and the article is reviewed in this newsletter (see 'In the literature ...').

The ANC prospective registry

Compared with the INC-EU prospective study, the ANC study is considering a broader range of tumour types, including breast, lymphoma, lung, colorectal, ovarian and 'other types' of cancer. The aim is to reach the target of 5,000 patients by spring 2005. Early data from the study were reported at ASCO 2004 (see Insight issue 4), and analyses of data collected between 2002 and 2004 were presented later in 2004 at the 46th Annual Meeting and Exposition of the American Society of Hematology (ASH). The group found that although the risk of

severe and febrile neutropenia varied depending on tumour type, the initial episode was most likely to occur in the first cycle of chemotherapy across all tumour types (Crawford *et al.* 2004). Furthermore, neutropenia decreased with age, most likely as a result of age-related reductions in RDI (Tahir *et al.* 2004).

Economic analysis

An economic analysis of prophylactic pegfilgrastim for patients on chemotherapy regimens with an FN risk of $\geq 20\%$ was presented at ASH 2004 (Eldar-Lissai *et al.* 2004). The analysis involved incorporation of recent randomised controlled trials (RCTs) and cost data into clinically relevant models to demonstrate that pegfilgrastim is cost-saving at levels of FN risk associated with common chemotherapy regimens ($< 20\%$).

Validation of the risk model proposed at ASCO 2004

The ANC has previously established a risk model for mortality in hospitalised adult cancer patients with FN based on the variables: age, cancer diagnosis, comorbidities and complications (Kuderer *et al.* 2004a). At ASH 2004 (Kuderer *et al.* 2004b), the model was validated in an independent population of 16,379 patients. The model showed excellent fit ($p < 0.0001$) and a high level of discrimination for inpatient mortality ($p < 0.0001$). Their validated model may therefore assist clinicians in deciding the appropriate cost-effective treatment for adult cancer patients.

Aims and activities of the ANC

The ANC study group, the US counterpart of INC-EU, is directed by American haematologists and oncologists Gary Lyman, MD, MPH, David Dale, MD and Jeffrey Crawford, MD. The remainder of the study group comprises biostatisticians and other medical professionals from around the world, coordinated at the James P. Wilmot Cancer Center, University of Rochester, N.Y.

Prof Lyman was a guest speaker at the recent INC-EU meeting, which took place in Vienna on 28 October 2004 (see previous section). In his talk, he emphasised the importance of attaining the required dose intensity and illustrated how easily the dose can be reduced to below 85% of the planned dose with just a couple of small delays or reductions. He reminded the group that, at least for CMF, a decrease below 85% ARDI (average relative dose intensity) resulted in a worse outcome and a reduction



Photograph of Prof. Lyman's team taken at his home. From left to right: Marek Poniewierski, MD, MS (biostatistician), Eva Culakova, PhD (biostatistician), Connie French (administrative staff to Dr Lyman in Rochester), Joanne Nanos, MS, EdS (former coordinator of the grant), Debra Wolff, MS, PCNP (project leader) and Gary Lyman. Missing are: Laura Stellato (administrative staff at the ANC Coordinating Centre in Albany, New York) and Michael Bigelow, MBA (current project administrator for the grant).

Update from scientific meetings

► **Data from the INC-EU retrospective and prospective studies**

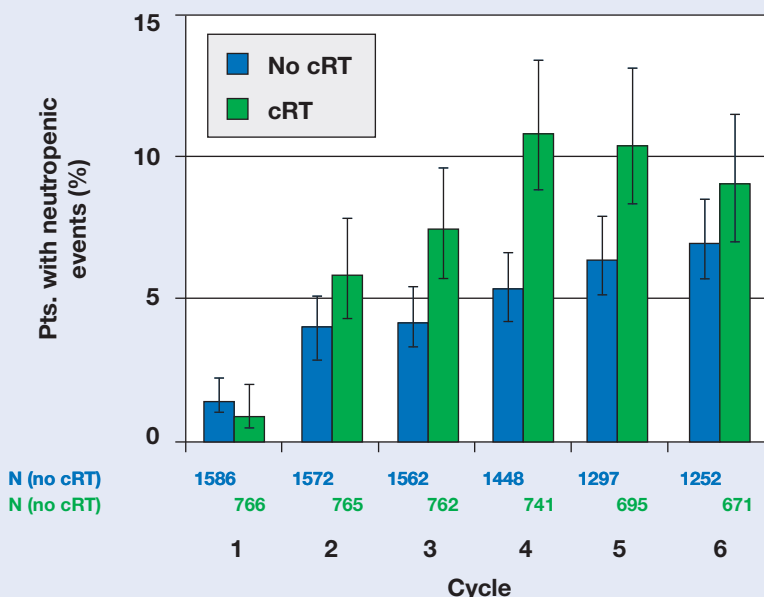
Concomitant radiotherapy (RT) is an independent risk factor for NE occurrence and reduced chemotherapy dose intensity

The message that concomitant radiotherapy (RT) is an independent risk factor for NE occurrence and reduced chemotherapy dose intensity was reported by **C. Jackisch** at the 23rd European Society for Therapeutic Radiology and Oncology (ESTRO 23) meeting (Jackisch *et al.* 2004).



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Incidence of neutropenic events by cycle without vs with concomitant radiotherapy (cRT) administration



Error bars show 95% confidence intervals

These conclusions were derived from the combination of data from five retrospective audits comprising 2,409 patients receiving chemotherapy for breast cancer between 1983 and 2001. Concomitant radiotherapy was used in 32% of patients and these patients were more likely to experience a NE (27% vs. 17% of those without concomitant RT ($p < 0.0005$)) and receive ARDI $\leq 85\%$ (21% vs. 14% of those without concomitant RT ($p < 0.0005$)).



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First presentation of the INC-EU Prospective Observational European Neutropenia Study

The first presentation of the INC-EU Prospective Observational European Neutropenia Study was made by **R. Pettengell** at the 9th International Primary Therapy of Early Breast Cancer conference in St. Gallen, 2005 (Pettengell *et al.* 2005). A poster presentation was made of the study design, methods and current status. The study will contribute to clarifying the occurrence and impact of chemotherapy-related neutropenia in the treatment of breast cancer and lymphoma patients. It is also expected to contribute to the development of clinical risk models enabling targeted prophylaxis. Recruitment is on course to be completed by April 2005.

News from the 29th Congress of the European Society for Medical Oncology (ESMO)

Prophylactic G-CSF significantly reduces febrile neutropenia

A European subgroup analysis of 529 patients enrolled in a phase 3 study investigating the effects of prophylactic pegfilgrastim on the incidence of FN in breast cancer patients receiving docetaxel (100mg/m² IV Q3W; 20010114) was presented by **Jagiello-Gruszfeld** at ESMO 2004 (Jagiello-Gruszfeld *et al.* 2004). Patients treated with pegfilgrastim on day 2 of each cycle experienced a 97% reduction in FN, a 94% reduction in FN hospitalisation and an 88% reduction in IV anti-infective use. This European data set showed no difference from the overall dataset (Schwartzberg *et al.* 2004) and suggests that pegfilgrastim dramatically reduces FN when used in the first and subsequent cycles of a chemotherapy regimen with an expected FN occurrence of approx. 20%.

Antibacterial prophylaxis has a beneficial effect in some tumour types

Cullen tackled the controversial issue of prophylactic antibacterials in a placebo-controlled, double-blind randomised trial of 500mg levofloxacin per day, for 7 days, covering the expected period of neutropenia in 1,565 patients with solid tumours or lymphoma. Levofloxacin reduced the febrile episode rate for cycle one in testicular, lung and breast cancer from 8% to 4% (χ^2 test; $p = 0.0002$), however, the efficacy was less for lymphomas (Cullen *et al.* 2004)

A dose-dense regimen with comparable efficacy and lower toxicity than conventional chemotherapy

Schuetz presented the results from a German phase 3 study comparing three-weekly docetaxel (75 mg/m²; the standard second-line CT for patients with advanced NSCLC) with a weekly docetaxel regimen (35 mg/m²). Neutropenia occurred in 20.6% of patients receiving 3-weekly CT but in only 4.8% of patients on the weekly regimen ($p \leq 0.001$). Overall, weekly docetaxel demonstrated an improved therapeutic index, better tolerability and a trend towards longer median survival than standard 3-weekly docetaxel (Schuetz *et al.* 2004).

A trend towards better outcomes for cancer patients; reduced mortality correlates with guideline implementation

An overview of breast cancer mortality trends over the past 20 years in Canada was presented by Ragaz (Ragaz *et al.* 2004). During this time, there has been a substantial reduction in mortality of between 10 and 15%. This trend occurred earlier and to a greater extent in British Columbia, where guidelines and 'Community Outreach' were implemented earlier than in other provinces, which suggests a correlation between mortality reduction and improved organisation of cancer care.

Announcement of forthcoming meetings

31st Annual Meeting of the European Group for Blood and Marrow Transplantation (EBMT); 21st Meeting of the EBMT Nurses Group; 4th Meeting of the EBMT Data Management Group
20 to 23 March 2005 – Prague, Czech Republic
www.akm.ch/ebmt2005

Annual Meeting of the American Society of Clinical Oncology (ASCO)
13 to 17 May, 2005 – Orlando, USA
www.asco.org

10th Congress of the European Haematology Association (EHA)
2 to 5 June 2005 – Stockholm, Sweden
www.eurocongres.com/eha2005

Scientific and Educational Conference (ESEC)
2 to 5 June 2005 – Budapest, Hungary
www.esmo.org/ESEC

9th International Conference on Malignant Lymphoma (ICML)
8 to 11 June 2005 – Lugano, Switzerland
www.lymphcon.ch

17th International Symposium of the Multinational Association for Supportive Care in Cancer (MASCC/ISOO)
30 June to 2 July 2005 – Geneva, Switzerland
www.mascc.org

13th European Conference on Clinical Oncology (ECCO)
30 October to 3 November 2005 – Paris, France
www.fecs.be/emc.asp

47th Annual Meeting and Exposition of the American Society of Haematology (ASH)
3 to 6 December, 2005 – New Orleans, USA
www.hematology.org

28th Annual San Antonio Breast Cancer Symposium (SABCS)
8 to 11 December, 2005 – San Antonio, USA
www.sabcs.org

5th European Breast Cancer Conference (EBCC)
21 to 25 March, 2006 – Nice, France
www.fecs.be/emc.asp

5th Spring Convention of the European Oncology Nursing Society (EONS)
20 to 22 April 2006 – Dresden, Germany
www.fecs.be/emc.asp

19th Meeting of the European Association of Cancer Research (EACR)
1 to 4 July 2006 – Budapest, Hungary
www.fecs.be/emc.asp

Abstracts from ESMO 2004 can be found in *Annals of Oncology* 2004; 15 Supplement 3. Details of the congress can be found at www.esmo.org/congress2004.

In the literature ...

This section of the Insight newsletter features selected recent publications relevant to the INC-EU.

► The CXCL12-CXCR4 chemotactic pathways as a target of adjuvant breast cancer therapies

Epstein RJ, *Nature reviews Cancer* 2004;4:1-9

In this review, Epstein discusses the potential role of the CXCL12 chemokine and its receptor, CXCR4, in the mechanisms for tumour micrometastasis and for hormonal and cytotoxic anti-cancer therapies.

Epstein suggests that the increase in circulating granulocyte colony stimulation factor (G-CSF) in response to moderate neutropenia and dose-dense chemotherapy could exert beneficial effects through CXCL12-CXCR4 regulation. Moderate neutropenia induces a compensatory increase in G-CSF due to secretion from

bone-marrow stromal cells, and dose-dense chemotherapy is facilitated by exogenous G-CSF support, as well as by release of endogenous G-CSF from damaged stromal and endothelial cells.

As well as inducing neutrophil proliferation, G-CSF induces neutrophil mobilisation into the bloodstream through the action of the serine protease DPPIV on CXCL12. Cleavage of this chemokine prevents its interaction with the CXCR4 receptor on the surface of neutrophils and permits their release from the bone marrow into the blood stream. Reduced concentration gradients of active CXCL12 are then no longer able to retain neutrophils in the bone marrow.

CXCR4 is not only expressed on the surface of neutrophils but is also frequently over-expressed in breast cancer cells. Furthermore, tissues to which breast cancer cells metastasize express CXCL12. Therefore the increase in G-CSF in response to either moderate neutropenia or administered with dose-dense chemotherapy could help prevent the micrometastasis of breast cancer cells. Since oestradiol induces the expression of CXCL12 in breast cells, irrespective of ER status, Epstein suggests that anti-hormonal treatments may also be successful in patients with ER-poor, CXCR4-positive disease.

► Incidence and predictors of low chemotherapy dose-intensity in aggressive non-Hodgkin's lymphoma: a nationwide study

Lyman GH *et al.*, *JCO* 2004;22(21): 4302-4311

It has been shown that the reduction of relative dose-intensity (RDI) below 85% of planned dose compromises the survival of cancer patients. This study assessed the incidence and risk factors for reduced RDI in patients with aggressive non-Hodgkin's lymphoma (NHL) using the data collected from 4,522 patients in 567 US practices.

The received dose intensity was compared with two separate standards; a minimum of 6 cycles and the National Comprehensive Cancer Network Guidelines. RDI \leq 85% occurred in 53% and 48% of patients respectively.

Between 1999 and 2001 an increase in the planned reduction of RDI was observed. Older patients not treated with colony stimulating factor (CSF) were significantly more at risk of reduced RDI and FN. The independent factors linked to reduced RDI were: age (\geq 60 years), advanced disease stage, poor performance status and no CSF use. In a previous study in patients with ESBC, Lyman *et al.* found similar predictive factors of reduced RDI, in particular, age (\geq 65 years) and no use of CSF in the first cycle (Lyman *et al.* 2003).

In conclusion, this study confirms that the prophylactic use of CSF in patients with aggressive NHL as soon as during the first cycle of treatment can significantly reduce the risk of neutropenic complications and decrease the risk of reduced RDI.

Lyman *et al.* propose that a risk model that identified the patients at high risk of FN would allow the use of prophylactic CSF to be targeted and for the full dose of chemotherapy to be given.

Update from the European Oncology Nursing Group

► Launch of the Titan Initiative across Europe

Four pilots of TITAN have now been tested in Ireland, France, the Netherlands and the UK. The pilot phase was attended with great enthusiasm by all participants (132 in total) and showed that the programme is well structured and corresponds to the needs for information on these haematological toxicities. A number of exciting dissemination projects has already been submitted and the final report should be completed in January 2005. TITAN remains on track for full implementation during 2005 and a dedicated TITAN website is currently being set up and will be accessible from the EONS website at <http://www.cancerworld.org/home.asp>.

Thanks to the continuing commitment and interest in TITAN, many national societies across the whole of Europe are becoming interested in implementing the project nationally, and Amgen has agreed to provide financial support for poorer countries.



Abbreviations

Abbreviations used in this newsletter are as follows:

ANC	Awareness of Neutropenia in Chemotherapy
ARDI	Relative Dose Intensity
ASCO	American Society of Clinical Oncology
ASH	American Society of Hematology
CHOP	Cyclophosphamide, doxorubicin, Vincristine, Prednisone
CIN	Chemotherapy-Induced Neutropenia
CMF	Cyclophosphamide, Methotrexate, 5-Fluorouracil
CSF	Colony Stimulating Factor
CT	Chemotherapy
EBCC	European Breast Cancer Conference
ECPM	European Centre of Pharmaceutical Medicine
EHA	European Haematology Association
EONS	European Oncology Nursing Society
ESBC	Early Stage Breast Cancer
ESMO	European Society for Medical Oncology
ESTRO	European Society for Therapeutic Radiology and Oncology
FN	Febrile Neutropenia
G-CSF	Granulocyte Colony Stimulating Factor
INC-EU	Impact of Neutropenia in Chemotherapy European study group
NAP	Neutropenia Audit Package
NE	Neutropenic Event
NHL	Non-Hodgkin's Lymphoma
NSCLC	Non-Small Cell Lung Carcinoma
RDI	Relative Dose Intensity
RT	Radiotherapy
RCT	Randomised Clinical Trials
SCLC	Small Cell Lung Carcinoma
TITAN	Training Initiative in Thrombocytopenia, Anaemia and Neutropenia

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► A possible future collaboration between Eons and INC-EU

On 15 December 2004, Ruth Pettengell joined EONS representatives in Brussels to discuss areas of common interest and the possibility of collaborating on a patient screening and management tool. During the meeting, Ruth Pettengell and Jan Foubert (president of EONS) were briefly interviewed.

Q1 How did you learn about the INC-EU/TITAN project?

JF. I met Ruth Pettengell at the ESMO congress in October 2004.

RP. I first learned about the project while I was attending a workshop in Copenhagen.

Q2 What are the common areas of interest between the aims of the TITAN project and the INC-EU?

JF. I believe that both EONS and the INC-EU are interested in:

- ensuring that uniform information is given to patients
- a better education of all healthcare professionals throughout Europe
- priority to be given to neutropenia

RP. There is common interest in:

- raising awareness of neutropenia for both patients and healthcare professionals
- expediting patient management
- improved/standardisation of information for patients and healthcare professionals
- creating an audit as a tool for education and changing practice

Q3 How would you imagine that EONS and the INC-EU could work together in the future?

JF. We would like to develop an easy-to-use screening and management tool for neutropenia (electronic). We could now write a joint proposal with INC-EU detailing the different phases of the study. We are also both interested in developing a paper-based audit tool. Data and information from the INC-EU Prospective Observational European Study would certainly assist development of future audit packages and patient tools.

RP. I believe there is a high potential for us to work together in the future. In particular, on a prospective randomised controlled trial (RCT) collecting patient symptoms, on a system for informing management in real-time of patient data and also a study of the timing of hospital management of neutropenic care. We could also work together to create uniformity of information given to patients and to expand patient education. I also fully support the TITAN initiative aimed at educating medical personnel. There should be a section for each group in each organisation's newsletter and website, and representation of each group, either regularly or for relevant meetings only.

For questions about TITAN, please contact either Jan Foubert, President of EONS. Email: fa108364@skynet.be or the EONS secretariat at eons@village.uunet.be.

► Details of Insight and the INC-EU Coordinating Centre

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