

학술논문 작성 시 최근 변화:

Transparency 원칙

출판윤리위원회 간사
인제의대 김 유 선

Transparency 이란?

- 투명성
- Describing all aspects of the research process, from planning, proposing, performing, and reporting
- **Transparency and accountability** are the fundamental principles for research integrity.

학술논문 작성 시 저자가 알아야 할 투명성

- 저자됨
- 이해관계 (Conflict of Interest: COI)
- 표절
- 중복출판, Text recycling
- 저작권
- Best Practice

저자 자격 요건

- **4가지 항목을 모두 충족할 경우로 권고**
 - 연구의 구상이나 설계에 **실질적인 기여**; 또는 자료의 획득, 분석, 해석
 - 연구 결과에 대한 논문 작성 또는 중요한 학술적 부분에 대한 **비평적 수정**
 - 출판되기 전 **최종본에 대한 승인**
 - 연구의 정확성 또는 진실성에 관련된 문제를 적절히 조사하고 해결하는 것을 보증하고, **연구의 모든 부분에 책임을 진다는 점에 동의**

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Original Article
Published online: November 12, 2018
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Knowledge and viewpoints on biosimilar monoclonal antibodies from members of the Asian Organization of Crohn's and Colitis: comparison with European Crohn's and Colitis members

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저자 자격 요건은 매우 중요

- **Did you check the COI form and coauthor signature for this manuscript?**
- **Dr. Hisamatsu and I were listed as coauthors, but we both know this article when it has been published**
- **We did not have the chance to check it and we both had not sign the co-authorship**

공저자 의견, 저작권 동의서 확인 후 편집위에서는 Withdrawn 결정

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[Intest Res.](#) 2018 Nov 12. doi: 10.5217/ir.2018.00084. [Epub ahead of print]

WITHDRAWN: Knowledge and viewpoints on biosimilar monoclonal antibodies from members of the Asian Organization of Crohn's and Colitis: comparison with European Crohn's and Colitis members.

[Park SK](#)¹, [Hisamatsu T](#)², [Ran Z](#)³, [Wei SC](#)⁴, [Park DI](#)¹.

Author information

Abstract
Ahead of Print article withdrawn by publisher.

KEYWORDS: Asia; Biosimilar pharmaceuticals; Infliximab; Knowledge

PMID: 30419639 DOI: [10.5217/ir.2018.00084](https://doi.org/10.5217/ir.2018.00084)

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저자 자격 기준이 안되면?

- ICMJE에서 요구하는 저자자격 기준을 한 가지라도 충족하지 못할 경우
- 기여자(non-author contributor)로 간주, **Acknowledgment** 에 표시
 - 연구비 획득, 연구 과정을 감독, 행정지원
 - 원고 정리를 포함한 단순한 원고 교정, 언어 교정
- Because acknowledgment may imply endorsement by acknowledged individuals of a study's data and conclusions, editors are advised to require that the corresponding author obtain written permission

저자됨 위반 종류

Type of Authorship Abuse	Description
Coercion authorship	Use of intimidation tactics to gain authorship. Arguably a serious form of scientific misconduct
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Mutual support authorship	Agreement by two or more investigators to place their names on each other's papers to give the appearance of higher productivity.
Ghost authorship	Papers written by individuals who are not included as authors or acknowledged.
Denial of authorship	Publication of work carried out by others without providing them credit for their work with authorship or formal acknowledgment. A form of plagiarism and therefore scientific misconduct.

저자 정하기

- 연구를 처음 기획할 때부터 또는 연구 진행과정 중 기준에 따라 저자됨을 설정
- 저자로 기록된 모든 연구자들이 네 가지 저자됨의 기준을 충족하는지를 판별하는 것은 **저자들의 공동책임**이며, 투고 받은 학술지의 책임이 아님
- 만약 저자들이 논문이 투고되었거나 출판된 이후에 특정 저자의 **철회 또는 추가를 요청**한 경우 학술지 편집인에게 **사유와 함께** 논문에 기록된 모든 저자들과 **철회 또는 추가 대상 저자가 서명한** 문서를 제출

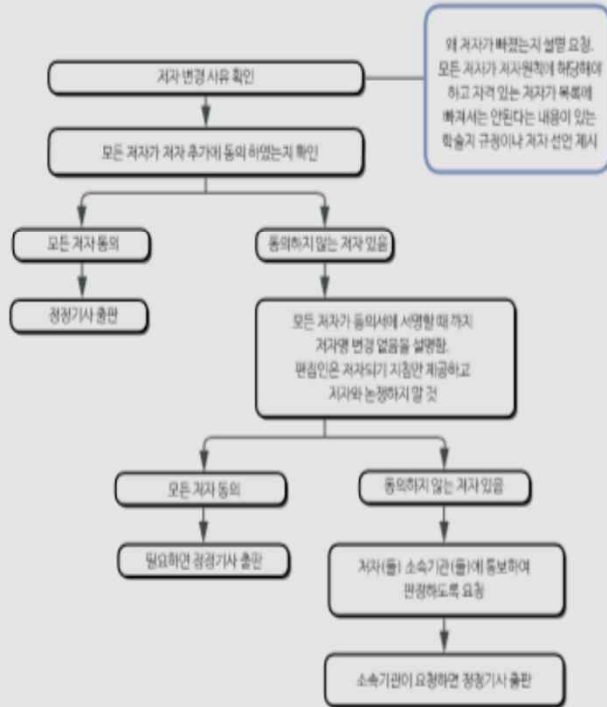
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(c) 출판 후 저자 추가 요청

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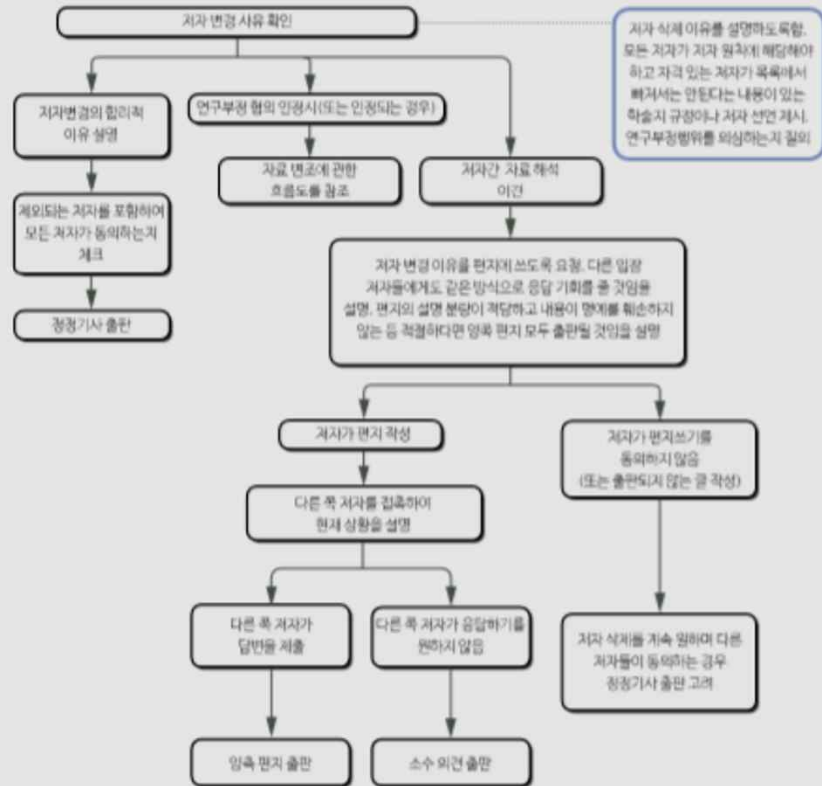


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저자 자격에 대한 분쟁 예방

- **Clinical Trial registration**
- **ORCID (Open Researcher and Contributor ID)**
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- **ICMJE authorship declare**

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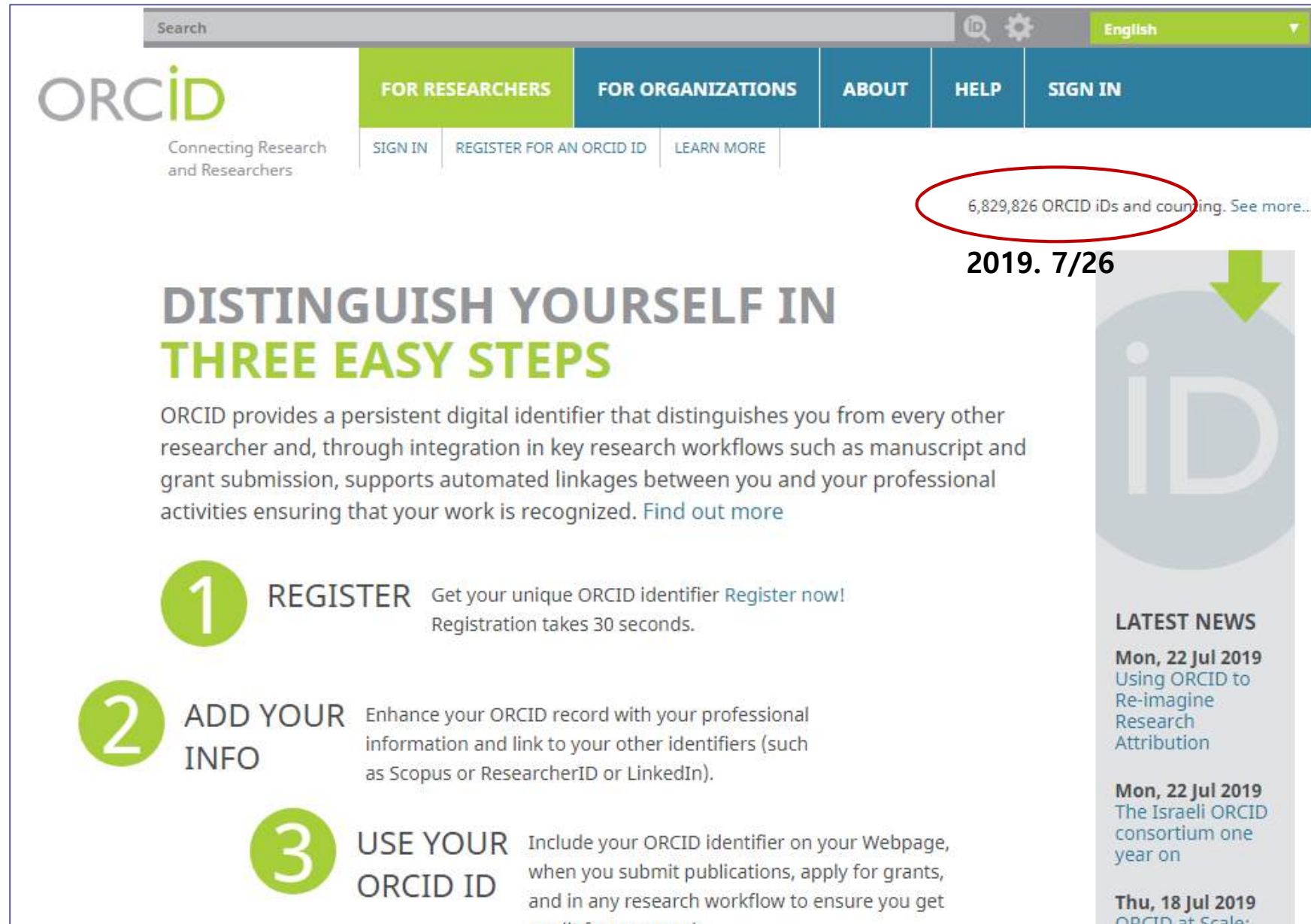
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You Sun Kim

ORCID ID

<https://orcid.org/0000-0002-5156-3458>

[인쇄 보기](#)

기타 ID

ResearcherID: B-2881-2015

▼ 직장 (1)

↑ 정렬

Inje University Seoul Paik Hospital: Jung-gu, Seoul

2000-03-02 까지 현재 | professor (Internal medicine)

Employment

소스: You Sun Kim

[우선 소스](#)

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Seoul National University College of Medicine: Seoul

2000-03-02 까지 2002-08-28 | Ph.D

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[우선 소스](#)

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1987-03-02 까지 1993-02-25 | M.D., PhD

Education

소스: You Sun Kim

[우선 소스](#)

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The Korean Journal of Gastroenterology

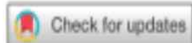
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DOI: [10.4166/kjg.2016.67.4.212](https://doi.org/10.4166/kjg.2016.67.4.212)

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Original Article
Preventive &
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Years of Life Lost due to Premature Death in People with Disabilities in Korea: the Korean National Burden of Disease Study Framework

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CRediT

- 각 저자의 역할을 taxonomy 분류 체계를 이용하여 표기하면 저자의 역할을 명확하게 알 수 있어 논문의 투명성을 높임 (14가지 역할)

Term	Definition
Conceptualization	<i>Ideas; formulation or evolution of overarching research goals and aims.</i>
Methodology	<i>Development or design of methodology; creation of models.</i>
Software	<i>Programming, software development; designing computer programs; implementation of the computer code and supporting algorithms; testing of existing code components.</i>
Validation	<i>Verification, whether as a part of the activity or separate, of the overall replication/reproducibility of results/experiments and other research outputs.</i>
Formal Analysis	<i>Application of statistical, mathematical, computational, or other formal techniques to analyse or synthesize study data.</i>
Investigation	<i>Conducting a research and investigation process, specifically performing the experiments, or data/evidence collection.</i>
Resources	<i>Provision of study materials, reagents, materials, patients, laboratory samples, animals, instrumentation, computing resources, or other analysis tools.</i>
Data Curation	<i>Management activities to annotate (produce metadata), scrub data and maintain research data (including software code, where it is necessary for interpreting the data itself) for initial use and later re-use.</i>
Writing – Original Draft	<i>Preparation, creation and/or presentation of the published work, specifically writing the initial draft (including substantive translation).</i>
Writing – Review & Editing	<i>Preparation, creation and/or presentation of the published work by those from the original research group, specifically critical review, commentary or revision – including pre- or post-publication stages.</i>
Visualization	<i>Preparation, creation and/or presentation of the published work, specifically visualization/data presentation.</i>
Supervision	<i>Oversight and leadership responsibility for the research activity planning and execution, including mentorship external to the core team.</i>
Project Administration	<i>Management and coordination responsibility for the research activity planning and execution.</i>
Funding Acquisition	<i>Acquisition of the financial support for the project leading to this publication.</i>

저자 기여도 표시

- **Conceptualization: AB**
- **Methodology: AB, CD, EFG.**
- **Formal analysis: EFG.**
- **Funding acquisition: AB.**
- **Project administration: AB.**
- **Visualization: CD, EFG.**
- **Writing - original draft: CD, EFG.**
- **Writing - review and editing: AB, CD, EFG.**
- **Approval of final manuscript: all authors.**

ORIGINAL ARTICLE

INTESTINAL RESEARCH

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<https://doi.org/10.5217/ir.2018.00022>
Intest Res 2019;17(1):70-77

Vitamin D deficiency is associated with disease activity in patients with Crohn's disease

Kyoung Ho Ko, You Sun Kim, Bo Kyung Lee, Jong Hyun Choi, Yong Moon Woo, Jin Young Kim, Jeong Seop Moon

Department of Internal Medicine, Seoul Paik Hospital, Inje University College of Medicine, Seoul, Korea

AUTHOR CONTRIBUTION

- ✓ **Conceptualization: Kim YS, Moon JS, Ko KH, and Lee BK.**
- ✓ **Methodology: Kim YS.**
- ✓ **Formal analysis: Kim YS, Ko KH, Choi JH, Woo YM, and Kim JY.**
- ✓ **Project administration: Kim YS.**
- ✓ **Visualization: Kim YS.**
- ✓ **Writing-original draft: Ko KH.**
- ✓ **Writingreview and editing: Kim YS.**
- ✓ **Approval of final manuscript: All authors.**

이해관계

- 이해관계를 밝히는 것은 **연구의 투명성 확보**를 위해 필수적
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국제의학학술지편집인협의회 (ICMJE) 이해관계 공개 양식



ICMJE Form for Disclosure of Potential Conflicts of Interest

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This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party – that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation or commercial sponsor, check "Yes".

3. Relevant financial activities outside the submitted work.

This section asks about your financial relationships with entities in the bio-medical arena that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work. You should disclose interactions with ANY entity that could be considered broadly relevant to the work. For example, if your article is about testing an epidermal growth factor receptor (EGFR) antagonist in lung cancer, you should report all associations with entities pursuing diagnostic or therapeutic strategies in cancer in general, not just in the area of EGFR or lung cancer.

Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. If there is any question, it is usually better to disclose a relationship than not to do so.

For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to be affected financially by the published work, such as drug companies, or foundations supported by entities that could be perceived to have a financial stake in the outcome. Public funding sources, such as government agencies, charitable foundations or academic institutions, need not be disclosed. For example, if a government agency sponsored a study in which you have been involved and drugs were provided by a pharmaceutical company, you need only list the pharmaceutical company.

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This section asks about patents and copyrights, whether pending, issued, licensed and/or receiving royalties.

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잠재적 이해관계의 공개를 위한 ICMJE 서식

Instructions

이 서식의 목적은 여러분의 일고를 읽을 독자가 어떻게 당신의 연구를 받아들이고 이해하는데 영향을 미칠 수 있는 당신의 이해관계에 관한 정보를 독자에게 제공하는 것이다. 이 서식은 전자방식으로 작성되고 전자방식으로 저장되게 만들어졌다. 이 서식은 데이터가 표시되도록 하는 프로그래밍을 포함하고 있다. 저자는 별도의 서식을 제출해야 하고 출판 정보 확인없이 작성되고 정확한 지에 대한 책임이 있다. 서식은 4부분으로 구성되어 있다.

1. 개인 식별 정보

실명을 기입하세요. 교신저자가 아닐 경우 "아니오"란에 표시하고, 다음 빈칸에 교신저자의 이름을 기입하시오. 요 청원은 링크에 대한 정보를 제공한다. 링크 번호를 다시 확인하고 기입한다.

2. 출판(Publication) 전 고려 사항

이 부분은 당신이 출판(publication)을 위해 투고한 연구 정보를 요구한다. 이 보고서를 작성할 때 의미하는 기간은 연구 자체 기간 즉, 초기 개념화부터 계획, 인정까지를 의미한다. 요청된 정보는 당신이 연구를 수행하기 위해 직접적이나, 소속 기관을 통해 간접적으로 지원받은 자원에 대한 것이다. "아니오"란에 표시하면 재 3차로부터 재정적 지원을 받지 않고 업무를 수행한 것을 의미한다. 이 경우 당신은 급여를 받은 기관으로부터 해당 업무의 지원을 받았으며, 그 기관은 재산자로부터 당신에게 돈을 지불되는 지원을 받지 않아야 한다. 만약 당신이 당신의 기관이 해당 업무를 지원하는 재산자(정부보조금 기관, 자선재단, 영리적 후원자)로부터 기금을 받았다면 "네"란에 표시한다. 유형과 지급대상(본인, 소속 기관, 아니면 당사 모두)에 대한 정보를 작성하시오.

3. 투고한 연구 이외의 관련 재정 활동

이 부분은 당신의 일을 작성하는데 영향을 줄 수 있거나, 잠재적으로 영향을 줄만한 생의학 분야에서 당신의 재정적 관계에 대해서 묻는다. 넓은 의미로 해당 업무와 이 연구 간에 관련 있는 모든 상호 관계에 대해 밝혀야 한다. 예를 들어, 투고한 논문이 폐암에서 삼피실장인자수용체(epidermal growth factor receptor, EGFR) 길관제와 관련된 실험이라면, 삼피실장인자수용체나 폐암 분야뿐 아니라, 일반적인 암의 진단 및 치료 전략을 추구하는 독립단체와의 관계를 모두 보고해야 한다.

연구 투고 전 36개월 동안의 자신의 수익, 즉 당사자에게 직접 제공되거나 소속 기관에 제공된 모든 수익과 지불 예정인 수익을 모두 보고한다. 이는 연구지원 단체에서 받는 지원금 뿐만 아니라 투고한 연구와 관련된 지원을 의도하여 제출한 연구 외의 업무 후원자의 본인과의 상호관계도 포함시킨다. 만약 의문의 여지가 있으면 관계를 밝히는 것이 그렇지 않은 것보다 좋다.

투고한 연구 이외의 일로 받은 보조금의 경우 게재된 연구가 재정적으로 영향을 준다고 인식될 수 있는 단체(예로 제약회사나 재단, 연구결과에 재정적 이해관계가 있다고 인식될 수 있는 단체가 지원하는 재단의 지원금 공개한다. 정부기관, 자선 단체나 학술단체로 받은 같은 공공 자금 지원은 공개하지 않아도 된다. 예를 들어, 정부기관이 당신 연구에 지원하고 약물을 제약회사에서 제공받은 경우 제약회사만 기재하면 된다.

4. 기타 관계

이 부분은 투고한 연구에서 당신이 기술한 내용에 영향을 주었다고 독자들이 인식하거나 잠재적으로 영향을 준다고 보이는 다른 관계나 활동에 대해 보고하기 위한 공간이다.

잠재적 이해관계의 공개를 위한 ICMJE 서식

Section 1. 개인 식별 정보

1. 이름 (First Name) 2. 성 (Last Name) 3. 유효일 (07-August-2008)

4. 당신이 교신저자입니까? 네 아니요

5. 링크 제목

6. 링크 고유번호 (링크 있다면 작성하시오)

Section 2. 출판 전 고려사항

당신 또는 당신 소속 기관은 투고된 연구에 대해 재3차로부터 어떠한 대가나 서비스(보조금, 데이터모니터링 위임, 연구 설계, 링크판매, 통계 분석 등을 받은 적이 있는가?

각 열에 대해서 "아니오" 또는 요청된 정보를 제공하시오. 한가지 이상의 관계가 있다면 "추가" 버튼을 누르고 값을 추가하시오. 불필요한 열은 "X"를 누르면 제거됩니다.

출판 전 고려 사항

유형	아니오	본인이 받은 돈	기관이 받은 돈*	단체 이름	연급할 내용**	
1. 보조금	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X 추가
2. 상담료 또는 사례비	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X 추가
3. 학회나 다른 목적의 여행의 지원	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X 추가
4. 검토활동 참여보상비(자료광시, 위임비, 통계분석, 결과위임비 등)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X 추가
5. 원고비 또는 원고검토비	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X ADD
6. 원고작성 지원, 약물, 장비 또는 행정지원	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X

이해관계 표시



REVIEW ARTICLE

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Intest Res 2019;17(1):45-53

INTESTINAL RESEARCH

Improving the quality of care for inflammatory bowel disease

Byong Duk Ye¹, Simon Travis²

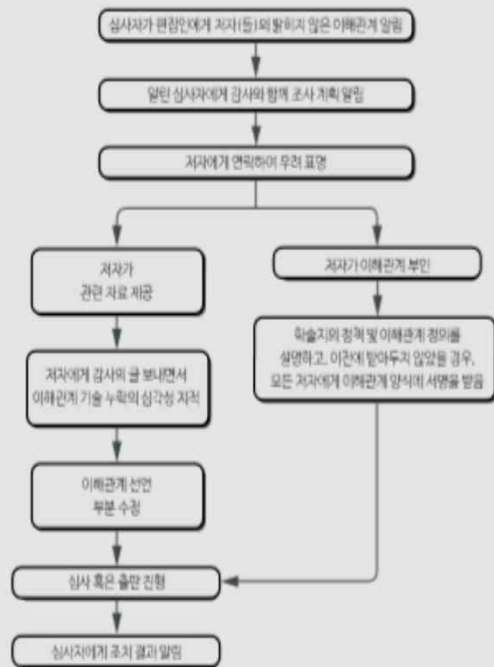
¹Department of Gastroenterology and Inflammatory Bowel Disease Center, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea; ²Translational Gastroenterology Unit, Oxford University Hospitals, Oxford, UK

CONFLICT OF INTEREST

BDY has received a research grant from Celltrion; consulting fees from Abbvie Korea, Celltrion, Daewoong Pharma., Ferring Korea, Janssen Korea, Kangstem Biotech, Kuhnle Pharm., Shire Korea, Takeda Korea, IQVIA, Cornerstones Health, and Roberts Clinical Trials Inc.; speaking fees from Abbvie Korea, Celltrion, Janssen Korea, Shire Korea, Takeda Korea, and IQVIA. However, all of these are not relevant to this article.

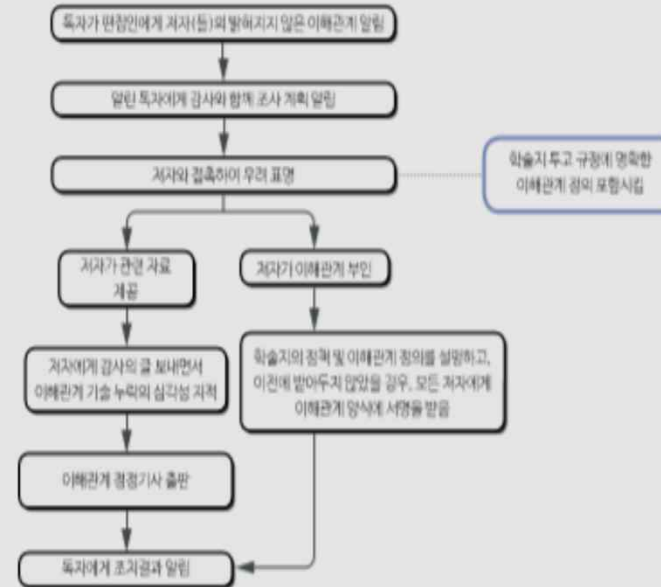
ST has received grant or research support from AbbVie, IOIBD, Lilly, UCB, Vifor, and Norman Collisson Foundation; consulting fees from AbbVie, Allergan, Amgen, Asahi, Biogen, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Chemocentryx, Cosmo, Enterome, Ferring, Giuliani SpA, GlaxoSmithKline, Genentech, Immunocore, Immunometabolism, Janssen, Lilly, Merck, MSD, Neovacs, NovoNordisk, Novartis, NPS Pharmaceuticals, Pfizer, Proximagen, Receptos, Roche, Shire, Sigmoid Pharma, Takeda, Topivert, UCB, VHSquared, Vifor and Zeria; and speaker fees from AbbVie, Amgen, Biogen, Ferring and Takeda. However, all of these are not relevant to this article.

투고 원고에서 밝히지 않은 이해관계가 의심될 때
What to do if a reviewer suspects undisclosed conflict of interest (Col) in a submitted manuscript



출판된 논문에서 밝히지 않은 이해관계가 의심될 때
What to do if a reader suspects undisclosed conflict of interest (Col) in a published article

Notes
이런 문제를 피하려면 출판 전 모든 저자에게 이해관계 양식에 서명을 받음



표절이란?

- “일반적 지식이 아닌 타인의 독창적인 아이디어 또는 창작물을 적절한 출처표시 없이 활용함으로써, 제 3자에게 자신의 창작물인 것처럼 인식하게 하는 행위”
- 타인의 연구내용 **전부 또는 일부를 출처를 표시하지 않고** 그대로 활용하는 경우
- 타인의 저작물의 단어·문장구조를 **일부 변형하여** 사용하면서 출처표시를 하지 않는 경우(**문장의 표절**)
- 타인의 **독창적인 생각** 등을 활용하면서 출처를 표시하지 않은 경우(**아이디어 표절**)
- 타인의 **저작물을 번역하여** 활용하면서 출처를 표시하지 않은 경우
- **표절은 한 언어를 다른 언어로 표현할 때도 적용되므로** 영어로 표현된 문서를 우리말로 번역할 경우에도 적용됨
- 300-500단어까지는 인용 가능, **500단어가 넘어가면** 저작권 승인 필요

‘연구윤리 확보를 위한 지침’ 제12조

아이디어 표절

- 영문 종설을 작성하면서 이미 출간되어 있는 기존 종설의 차례나 내용과 유사하게 작성하였지만, 동일한 단어, 표현을 자제하여 CrossCheck 유사도가 4% 밖에 되지 않은 경우 표절에 해당하는가?

답변: 표절의 유형에는 그대로 복사하는 **verbatim**, 같은 틀과 문장을 다른 문구로 표현하는 **paraphrasing**, 요약하는 **summarizing** 이 있다. CrossCheck 유사도가 4% 정도로 낮은 편이고 논문의 내용전개, 글의 전개순서와 내용이 표절의 의심을 사지 않도록 표현하였지만, 원본과 동일한 내용을 기술하고, 논문 일부에서 원저자의 주관적인 표현을 인용 없이 그대로 사용하고 논문의 다른 부분에는 원본에 없는 다른 내용을 첨가하여 전혀 다른 논문처럼 인식되게 한 점 등을 고려하면 허락이나 인용 없이 기존 종설을 발행한 원저자의 논문을 모방한 것으로 **paraphrasing** 유형의 중대한 표절로 보는 것이 타당하다.

표절 정도 판정

- **중대한 표절:** 많은 문장이나 자료를 저작권자의 허락없이 사용하고, 마치 자신이 작성한 것 처럼 제시한 경우
- **경미한 표절:** 고찰의 짧은 부분복사와 같은 정도 수준
- 표절은 **한 언어를 다른 언어로 표현할 때도** 적용되므로 영어로 표현된 문서를 우리말로 번역할 경우에도 적용됨

Similarity Check

- 표절 선별
- iThenticate software가 CrossRef, PubMed에 있는 전문 검색하여 논문간 유사성 비교
- 프로그램이 전체 내용을 비교 단위“fingerprint”로 만듦
- 유사성에 대한 보고“percentage overlap”
- 해석이 중요

Similarity Check: case 1

Introduction

⁶ Ascites is the pathological accumulation of fluid in the peritoneal cavity. Liver cirrhosis (~80% of cases) ⁵ is the most common cause of ascites. Malignant conditions (including peritoneal carcinomatosis) and benign conditions (including tuberculous peritonitis, heart failure, pancreatic disease, and renal disease) also contribute to the generation and accumulation of ascites. ¹⁴ Malignant ascites accounts for approximately 10% of all cases of ascites.¹ Several parameters for the diagnosis of malignant ascites have been studied, including protein levels in ascites, the ¹¹ ascites/serum concentration ratio of protein (protein A/S), lactate dehydrogenase (LDH) levels in ascites, the ¹¹ ascites/serum concentration ratio of LDH (LDH A/S), ²² carbohydrate antigen 19-9 (CA 19-9) in ascites, ²⁹ the serum-ascites albumin gradient (SAAG),⁴ fibronectin in ascites, and cholesterol in ascites.⁵ However, until now there have been no parameters which can completely differentiate the cause of malignant ascites, and ⁶ the gold standard for the diagnosis of malignant ascites is the presence of tumor cells in ascites.⁶ The specificity of this method is very high, but it has low sensitivity (40% to 60%) due to ¹ the lack of cell exfoliation common to all malignancies.³ This low sensitivity sometimes leads to invasive procedures, including laparoscopy, to acquire peritoneal tissues. The assessment of carcinoembryonic antigen in ascites (aCEA) has been suggested as an option to diagnose patients with ascites, and some studies have reported on the diagnostic value of aCEA.^{3,7,8} Those studies evaluated the diagnostic value of aCEA for various malignant cases, but there were few data for colorectal cancer (CRC) ⁵ patients with peritoneal carcinomatosis.

Diagnostic value of carcinoembryonic antigen in ascites for colorectal cancer with peritoneal carcinomatosis

ORIGINALITY REPORT

23%

SIMILARITY INDEX

PRIMARY SOURCES

- ¹ Kaleta, Erin J., Nicole V. Tolan, Karl A. Ness, Dennis O'Kane, and Alicia Algeciras-Schimmich. "CEA, AFP and CA 19-9 analysis in peritoneal fluid to differentiate causes of ascites formation", *Clinical Biochemistry*, 2013. 50 words — 2%
Crossref
- ² Yajima, K.. "Clinical and diagnostic significance of preoperative computed tomography findings of ascites in patients with advanced gastric cancer", *The American Journal of Surgery*, 200608. 40 words — 2%
Crossref
- ³ repository.ubn.ru.nl. 37 words — 2%
Internet
- ⁴ onlinelibrary.wiley.com. 35 words — 2%
Internet
- ⁵ Runyon, Bruce A.. "Ascites and Spontaneous Bacterial Peritonitis", *Sleisenger and Fordtran s Gastrointestinal and Liver Disease*, 2010. 31 words — 1%
Crossref

Similarity Check: case 2

¹ morbidity. It requires urgent and comprehensive assessment because a serious medical condition may be the underlying cause. Careful medical history taking, investigation of medications taken that can cause constipation, and physical examinations, including rectal examination, are important in all patients with severe constipation to define the type of constipation and direct the physician to the correct diagnosis, treatment, and intervention. ³ The use of retrograde cleansing enema is common in the treatment of chronic constipation. The effectiveness of enemas is dependent on several mechanisms. By distending the rectum, all enemas stimulate the colon to contract and eliminate stools. Adverse events caused by cleansing enemas are rarely reported in the literature but may be life-threatening. Perforation occurs with a colon ¹ full of fecal material and carries a high risk of peritoneal leakage and peritonitis. The most frequently reported cause of perforation in patients who receive enemas is the device tip; other causes are related to ¹⁰ localized weakness of the rectal wall, obstruction, or the patient's position during enema administration.²

¹ A cleansing enema is contraindicated in patients with fecal stones, rectal obstruction by a tumor or rectal prolapse, or active coronary heart disease and in comatose or noncompliant patients. In addition, enema should be avoided in patients with cancer treated with chemotherapy and in other immunocompromised patients, particularly those with severe neutropenia.

In the present cases, colorectal perforation was diagnosed on the basis of medical history, plain abdominal radiography findings, CT scans, and endoscopy. ² In the elderly, a careful review of the patient's recent treatment history is important. In the appropriate clinical context, if an enema has been recently given, the clinician should be aware of the potential complications of the procedure. Clinical indicators of the development of these complications include pain and bleeding. The rectum is insensitive to pain, and if significant discomfort follows an enema, then, leakage of colonic contents or the enema solution itself

Rectal Perforations Caused by Cleansing Enemas in Chronically Constipated Patients: Report of 2 Cases

ORIGINALITY REPORT

61%

SIMILARITY INDEX

PRIMARY SOURCES

- ¹ www.dovepress.com
Internet 241 words — 17%
- ² Ravi K. Bobba. "SEPTIC SHOCK IN AN ELDERLY PATIENT ON DIALYSIS: ENEMA-INDUCED RECTAL INJURY CONFUSING THE CLINICAL PICTURE", *Journal of the American Geriatrics Society*, 12/2004
Crossref 170 words — 12%
- ³ Haim Paran. "Enema-induced perforation of the rectum in chronically constipated patients", *Diseases of the Colon & Rectum*, 12/1999
Crossref 123 words — 9%
- ⁴ www.wjgnet.com
Internet 109 words — 8%
- ⁵ Lee, Seok Youn, Jung Nam Kwon, and Keun Young Kim. "Acute Peritonitis Caused by a Fibrosarcoma of the Transverse Colon in an Adult", *Annals of Coloproctology*, 2014.
Crossref 88 words — 6%
- ⁶ G. Gayer. "Perforations of the rectosigmoid colon induced by cleansing enema: CT findings in 14 patients", *Abdominal Imaging*, 07/01/2002
Crossref 48 words — 3%

Similarity Check: case 3

Introduction

²⁰ Inflammatory bowel disease (IBD), including Crohn's disease (CD) and ulcerative colitis (UC)

is a chronic, relapsing inflammatory disorder involving the gastrointestinal (GI) tract.¹ Although the etiology of IBD is still unknown, dysregulated mucosal immune response to gut microbiota is thought to play an important role in the pathogenesis of IBD.² Tumor necrosis factor alpha (TNF- α), one of the most important cytokine in the immune-mediated defense, is a major pathological cytokine in IBD by activating the nuclear factor- κ B transcription factor family.³ As the role of TNF in the pathogenesis of IBD has been revealed, anti-TNF therapy have been widely used in the treatment of IBD as new therapeutic agent. The efficacy of anti-TNF therapy for the induction and maintenance of remission in IBD has been demonstrated in a number of randomized clinical trials and meta-analysis.⁴⁻⁷

However, TNF- α also plays an important role in host defense against *Mycobacterium tuberculosis* (TB) by granuloma formation. As a result, the risk of developing TB increases in the patients treated with anti-TNF antibodies.⁸ Anti-TNF therapy, including monoclonal antibodies such as infliximab and adalimumab, is known to increase the risk of latent TB infection (LTBI) reactivation by about 2 to 8-fold.^{9, 10} For this reason, the guidelines for the treatment of IBD recommend that screening for latent TB by a combination of patient history, chest X-ray, tuberculin skin test and interferon-gamma release assays (IGRA) should be performed prior to anti-TNF therapy.^{9, 11, 12}

Despite rapid economic growth, South Korea still has a high burden of TB.¹³ The incidence of TB and the estimated prevalence of LTBI in South Korea are both higher than those in developed countries.^{6, 12, 14}

⁷ between the two groups. There were no significant differences in TB progression between the two groups in terms of cure rate, mortality, and recurrence rate after cure. Active TB was cured in 24 (96.0%) patients in the IBD group and in 70 (93.3%) in the non-IBD group ($p=0.409$). The rate of side effects of anti-TB medications in the IBD group did not differ from that observed in the non-IBD group (7 (28.0%) IBD patients vs. 15 (20.0%) non-IBD patients; $p=0.403$). Side effects of anti-TB medications were observed in 7 (28.0%) in IBD patients and 15 (20.0%) in non-IBD patients ($p=0.403$). TB-related mortality rates in both groups was about 2% (1 (4.0%) IBD patients vs. 1 (1.3%) non-IBD TB patients; $p=0.439$).

Five of the 25 patients maintained anti-TNF therapy during anti-TB treatment and additional 3 patients resumed anti-TNF therapy after completion of the anti-TB treatments. The remaining 17 (68.0%) patients did not restart anti-TNF therapy after the anti-TB treatments were completed. There was no recurrence of TB among patients who resumed anti-TNF therapy

Discussion

³⁹ This is the first study from South Korea to evaluate the clinical prognosis of TB in IBD patients with anti-TNF therapy compared to general population. Although anti-TNF- α therapy has been believed to increase the risk of TB infection in IBD patients, there have been no studies on the clinical course of TB in IBD patients compared to general population. In our study, the characteristics of TB in IBD patients treated with anti-TNF therapy differed from those of the non-IBD patients in terms certain laboratory and the frequency of positive smear results for acid-fast bacilli at diagnosis of TB. However, the clinical course of TB in the IBD patients treated with anti-TNF therapy did not differ significantly from that

observed in the non-IBD patients in terms of cure rate, mortality, and recurrence rate after cure. Therefore, our study provides evidence that the clinical prognosis of TB in the IBD patients receiving anti-TNF- α therapy is not poor compared to the general population.

Despite rapid economic growth, the incidence of tuberculosis in Korea is still high. According to the World Health Organization, the incidence of TB in South Korea was 80 cases per 100,000 population in 2015, which is higher than other countries among high-income countries. As the number of IBD patients in South Korea increases, the recurrence of TB due to the use of anti-TNF, as an IBD treatment, is a major concern. Recent study using a nationwide population-based study in South Korea has been reported.²⁰ TB incidence rate in IBD patients treated with anti-TNF therapy was significantly higher than that in all IBD patients using the 2011–2013 data of the South Korean National Health Insurance system. In this study, the TB incidence ratio among IBD patients prescribed 5-ASA, corticosteroids, immunomodulators and anti-TNF therapy were 143.5, 208.5, 284.6 and 554.1 per 100,000 person-years, respectively. The risk of TB is higher in patients with IBD, especially in patients with CD and patients receiving anti-TNF therapy.

In our study, the incidence of active TB during anti-TNF therapy in IBD patients was similar to that reported in other Korean studies.^{8, 20, 21} According to the previous studies, the risk of TB infection in patients using biological agents is more than 50 times higher than in the general population.^{22, 23} Previous study in South Korea conducted with 873 IBD patients receiving anti-TNF therapy reported that the risk of TB in IBD patients receiving anti-TNF therapy was 41 fold higher than that in the matched general population.⁸ A population-based study published in 2017 showed that patients with IBD, particularly those with CD, and those receiving anti-TNF- α therapy had a higher risk of TB with an incidence of 554.1 per 100,000

Clinical features and outcomes of tuberculosis in inflammatory bowel disease patients treated with anti-TNF therapy

ORIGINALITY REPORT

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- 1 "Abstracts", *Journal of Gastroenterology and Hepatology*, 2016
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- 3 S. N. Hong, H. J. Kim, K. H. Kim, S.-J. Han, I. M. Ahn, H. S. Ahn. "Risk of incident infection in patients with inflammatory bowel disease: a nationwide population-based study in South Korea", *Alimentary Pharmacology & Therapeutics*, 2016
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- 5 Byun, Ja Min, Chang Kyun Lee, Sang Youl Rhee, Hyo-Jong Kim, Jong Pil Im, Dong Il Park, Chang Soo Eun, Sung-Ae Jung, Jeong Eun Shin, Kang-Moon Lee, and Jae Hee Cheon. "Risks for opportunistic tuberculosis infection in a cohort of 873 patients with inflammatory bowel disease receiving a tumor necrosis factor- α inhibitor", *Scandinavian Journal of Gastroenterology*, 2015.
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- 6 Lee, Jang Wook, Chang Hwan Choi, Ji Hoon Park, Jeong Wook Kim, Sang Bum Kang, Ja Seol Koo, Young-Ho Kim, You Sun Kim, Young Eun Joo, and Sae Kyung
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해석

1. JGH 초록과 동일한 내용(저자 초록)
2. 전반적으로 고찰에서 타 논문과 동일한 문장 사용
3. 500단어 이상 동일하면 표절
4. 원저의 경우 40% 이상이면 심사 진행하지 않음

중복출판이란?

- 이미 출판된 논문과 상당 부분 겹치는 내용을 인용 없이 다시 출판하는 경우
- 중복 출판은 엄격히 금지되는 비과학적 행위
- 중복 출판은 심사활동, 편집활동, 학술지 공간 등의 자원이 낭비되고
- 논문의 수, 표본의 수를 늘려서 결과를 과대평가하게 하며
- 저작권을 침해(학술지에 게재된 논문의 저작권은 저자가 아니라 학술지가 갖게 됨)

중복 출판의 종류

- 이중게재(copy): 두 논문 간에 표본과 결과가 동일, 동일 논문을 투고한 경우
- 분할 출간(salami publication), 논문 쪼개기: 동일한 표본을 대상으로 결과가 다른 논문을 작성, 연구 결과가 겹치기도 함. 자료의 분절(fragmentation)이 문제가 됨
- 덧붙이기 출판(imalas publication): 표본은 다르지만 결과가 동일, 연구 대상자를 늘리거나 줄여서 논문을 쓰는 형태
- 표본과 결과가 상이함: 가장 복잡한 유형의 중복 출판으로, 저자와의 접촉을 통해서만 확인할 수 있음

JAMA 2004;291:974-980

중복출판이 발생하는 이유

- 동시에 두 학술지에 투고한 경우, 심사과정에서 발견하기 쉽지 않음
- 투고하는 연구자가 언어가 다르면 중복출판이 아니라고 믿고 있음
- 중복출판임을 알면서도 연구비 보고용 또는 승진이나 재임용 위해 투고하는 경우
- 중복출판이 출판윤리에서 문제가 되는 이유를 모르거나,
- 복제가 아닌 분절출판이나 덧붙이기출판도 중복출판인지 모르는 경우

이중 투고

Review status	
2019-A031	
Step 1 : Type, Title &	
MS ID	
** Manuscript Type	
** Major field	
Status	
** Title	
Running Title	
** Abstract	<p>2017, the scores of all SF-12 dimensions, reflected generic HRQL, were remarkably lower, compared indirectly with previously reported scores in the general population. The Mayo score, C-reactive protein level, and white blood cell count showed significant negative association with the IBDQ score (P <0.05). Conclusions: Psychosocial screening and timely interventions should be incorporated into the initial care of newly-diagnosed patients with UC.</p>
** Keywords	Ulcerative Colitis, Patient Reported Outcome Measures, Quality of Life, Anxiety, Depression

Instructions	Details	Fill Out Review Form	
Status in Review			
::: 1st Review :::			
Editorial Comment (Edit) EDIT			
Reliance Date	2019-06-07 11:17:46	Response Date	2019-06-28 19:09:32
Recommendation	Rejection without external review * English proof reading is required? No		
Comments to the Author	<p>Dear the Authors</p> <p>We found out duplicate submission was attempted without proper disclosure to the editor.</p> <p>Based on research ethics of our journal, the Council decides a disciplinary measure.</p> <p>Because your paper is a duplicate submission in the prepublication phase, your paper has been rejected.</p>		
Files	None (or N/A)		
	<p>time of diagnosis of ulcerative health-related quality of life e affiliated with the nationwide, patients were assessed using the ment (WPAI) questionnaire, survey (SF-12). Multiple linear etween Aug 2014 and Feb 2017, logical interventions, defined by atients. Patients with severe disease were more likely to have presenteeism, loss of work productivity, and activity loss, compared to those with moderate disease (all p-value <0.05). Significant mood disorders had the strongest negative relationships with the total IBDQ score, which reflected disease-specific HRQL (β coefficient = -22.1 for depression and -40.0 for anxiety, p-value <0.001). The scores of all SF-12 dimensions, reflected generic HRQL, were remarkably lower, compared indirectly with previously reported scores in the general population. The Mayo score, C-reactive protein level, and white blood cell count showed significant negative association with the IBDQ score (p-value <0.05). Conclusions: Psychosocial screening and timely interventions should be incorporated into the initial care of newly-diagnosed</p>		

2019. 6/5 투고

2019. 4/1 투고

Six criteria of duplicate publication

항목	설명
유사한 가설	가설 중 인구집단 관련, 독립, 종속 변수가 거의 동일
유사한 표본 수	연구 재료, 실험동물, 대상자의 90% 이상이 동일
동일하거나 거의 동일한 방법	자료 수집, 분석, 제시 방법이 같거나 거의 같음
유사한 결과	결과가 양이나 질 측면에서 거의 동일
동일한 저자	최소한 1명의 동일한 저자
새 정보가 거의 없는 경우	추가적인 지식이 거의 추가되지 않은 경우

분절 출간(salami publication)

- 한 군주에서 항균제 내성관련 효소가 5개 발견되었다. 일반적으로 한 효소의 성상 규명만으로도 하나의 논문이 되기에 이들 효소를 각각 나누어 보고할 경우, 한 군주에서 발견되었기에 중복출판에 해당하는가?

답변: 중복출판의 기준 중 '한 군주에서 항균제 내성 관련 효소'라는 범위로 동일 결과에 속한다. 비록 5가지 다른 효소가 발견되었으나, 이는 각각 하나씩의 의미를 부여할 새로운 발견의 의미가 아닐 것이다. 따라서 5개 효소를 함께 묶어서 발표되어야 가치가 있을 것이다. 따라서 각각을 분리하면 분절출판과 나아가 내용의 표절이 될 가능성이 높다. 연구에서 얻어진 자료를 출판할 때 고려할 것은 1) 결과를 하나의 논문으로 만들 수 있는지, 즉 하나의 논문으로 작성할 경우 주제가 달라져서 어색한 논문이 되는지가 고려되어야 하고, 2) 독자에게 하나의 논문으로 지식을 제공하는 것과 따로 나누어 제공하는 것이 어느 것이 좋은 지가 고려되어야 한다. 한 개의 논문으로 작성 가능하고 한 번에 독자에게 정보를 제공하는 것이 좋는데 나누어 출판하는 것은 윤리적이지 못하다.

분절 출간이 필요한 경우

- 분절 출간이 필요: 자료가 방대하여 한 번에 출판하기에 주제가 다양한 경우
- 코호트 연구, 수천 - 수만 명 자료, 여러 질병 분야
- 대상 및 방법에서 중복되는 내용은 앞의 논문을 그대로 인용하고, 코호트 연구 일부 내용이라는 것을 서론에서 밝히도록
- 대상은 같더라도 분석 방법이 달라지는 경우이므로 다른 결과
- 두번째 논문부터는 앞의 논문에서 기술한 것을 전부 참고문헌으로 인용한다면 반복하여 기술할 필요가 없음
- 새로운 내용을 강조하여 기술하고 고찰에서 의의를 다루는 것이 필요

CONNECT 연구

COMMENTARY

INTESTINAL RESEARCH

ISSN 1598-9100(Print) • ISSN 2288-1956(Online)
http://dx.doi.org/10.5217/ir.2014.12.3.173
Intest Res 2014;12(3):173-175

Crohn's Disease Clinical Network and Cohort (CONNECT) Study: The First Step Toward Nationwide Multicenter Research of Crohn's Disease in Korea

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20. Cheon JH, Kim YS, Ye BD, et al. Crohn's Disease Clinical Network and Cohort (CONNECT) study: the first step toward nationwide multicenter research of Crohn's disease in Korea. Intest Res 2014;12:173-175.

Original Article

Long-term Clinical Outcomes of Urban Versus Rural Environment in Korean Patients with Crohn's Disease: Results from the CONNECT Study



Doh et al. *BMC Gastroenterology* (2015) 15:31
DOI 10.1186/s12876-015-0262-x



RESEARCH ARTICLE

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The clinical characteristics of patients with free perforation in Korean Crohn's disease: results from the CONNECT study

PLOS ONE

RESEARCH ARTICLE

Clinical Factors and Disease Course Related to Diagnostic Delay in Korean Crohn's Disease Patients: Results from the CONNECT Study

Journal of
Gastroenterology
and Hepatology



doi:10.1111/jgh.13169

GASTROENTEROLOGY

Crohn's disease prognosis and early immunomodulator therapy: Results from the CONNECT study

덧붙이기 출판(imalas publication)

- 두 논문(A, B)은 코호트 대상군에서 같은 간암 발생요인에 대해 분석하였다. 두번째 B 논문은 첫번째 A 논문에서 분석한 간암 발생요인으로 공복시 혈당 요인외에 대사증후군 지표를 추가하여 분석하였다. B 논문에서 먼저 출판한 A 논문의 '대상'이 B 논문에 포함되었으나 이를 밝히지 않고 있다. 그러나 참고문헌에서는 A 논문을 인용하고 있는 경우 중복출판에 해당하는가?

답변: 원칙적으로 덧붙이기 출판이다. 논문의 가장 중요한 부분이 같은 내용이므로 이미 유사한 연구를 발표한 바 있고, 추가 연구가 진행되었다는 사실이 서론에 기재 되었어야 한다. 또한 서론에서 이미 알려진 사실로 일차 연구 결과가 소개되고 부족한 부분이 무엇인지를 밝히고 추가연구가 진행된 당위성을 밝혀야 한다. 대상의 중복여부 역시 언급해야 한다.

덧붙이기 출판이 가능하려면..

- 덧붙이기 출판은 처음 연구결과에 비교하여 **비록 대상이나 기간이 늘어나도 결과에 유의한 차이가 없다면 단신(brief report)로 처리하여 추후 조사에서 같은 결과가 나왔다고 간단히 기술**
- 처음 논문을 단신으로 처리하고 나중에 대상이나 기간을 늘려서 원저로 기술
- 이 경우 처음 논문을 인용하여 처음 논문에 나온 목적이나 대상, 기간 등의 내용 중 **바뀐 내용만 짧게 기술하고 나머지는 모두 참고문헌으로 처리**
- 관찰기간만 늘인 내용에서 원 논문과 다른 새로운 소견이 나와서 그 새로운 소견이 기록할 만한 가치가 있다고 편집인이 판단하면 게재가 가능

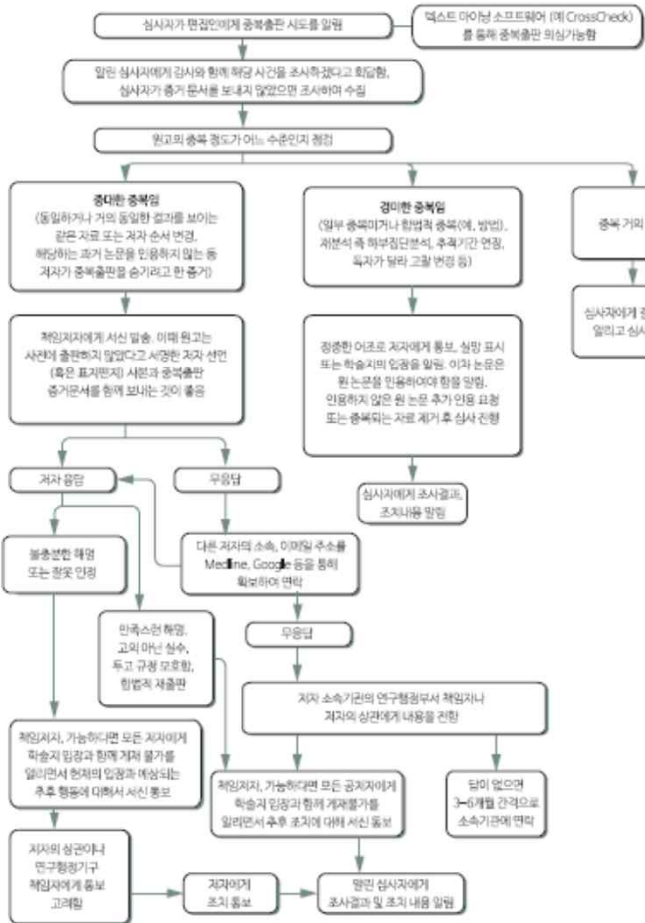
중복 출판 판정

- **경미한 중복 출판:** 일부 중복이 있지만 그 정도가 경미한 것
(예: 하위 집단, 추적관찰 기간 연장, 독자가 달라 고찰 변경 등)
- **중대한 중복 출판:** 중복이 있고 그 정도가 중대한 것
(예: 동일하거나 거의 동일한 결과를 보이는 같은 자료 또는 저자 순서 변경, 과거에 출판한 논문에 대한 **인용 누락** 등 **중복 게재 은폐 의혹** 등)

중복출판

(a) 투고된 원고의 중복출판 의심

Suspected redundant publication in a submitted manuscript



Notes
 • 투고 규정에 학술지가 중복출판 문제를 어떻게 다루는지 기술되어 있어야함
 • 해당 기관의 중복출판 규정을 표명하는 것이 도움이 될 수 있음
 • 저자가 중복출판을 하지 않았다는 윤서에 서명하도록 함
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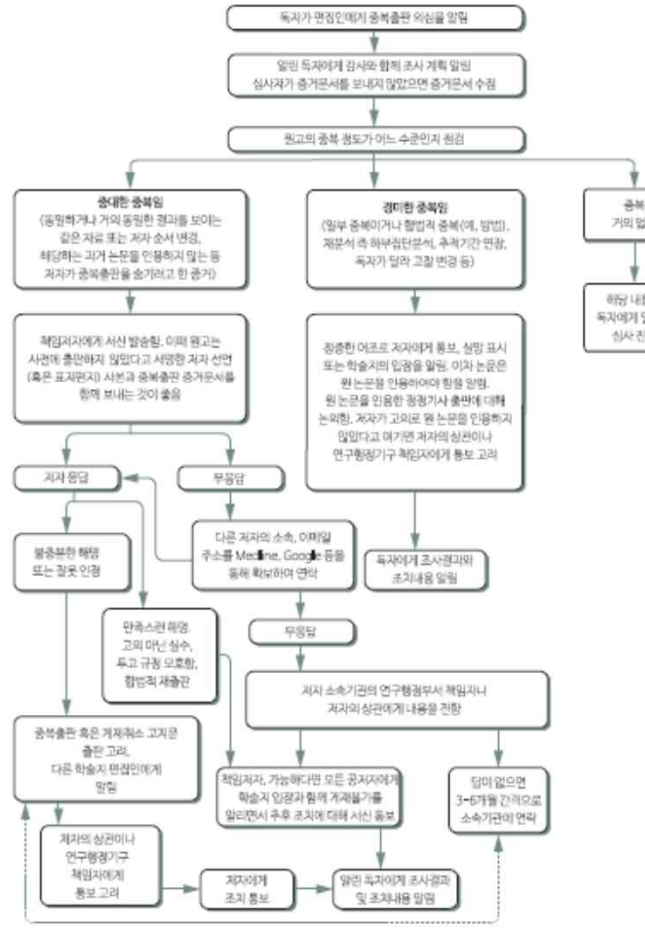
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연락처
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 2015년 11월 개정판

중복출판

(b) 출판 후 중복출판 의심

Suspected redundant publication in a published manuscript



Notes
 • 투고 규정에 학술지가 중복출판 문제를 어떻게 다루는지 기술되어 있어야함
 • 저자가 선인용에 서명하거나 체크박스에 체크하도록 하는 것이 추후 조사에 도움이 됨
 • 저자가 중복출판을 하지 않았다는 윤서에 서명하도록 함
 ICMJE는 방위언어인용(방위언어), 원논문을 반드시 인용하도록 권고. 방위언어만 게재 취소 혹은 중복출판 고지문을 출판하기 보다 중형기사 출판을 고려할 수 있음

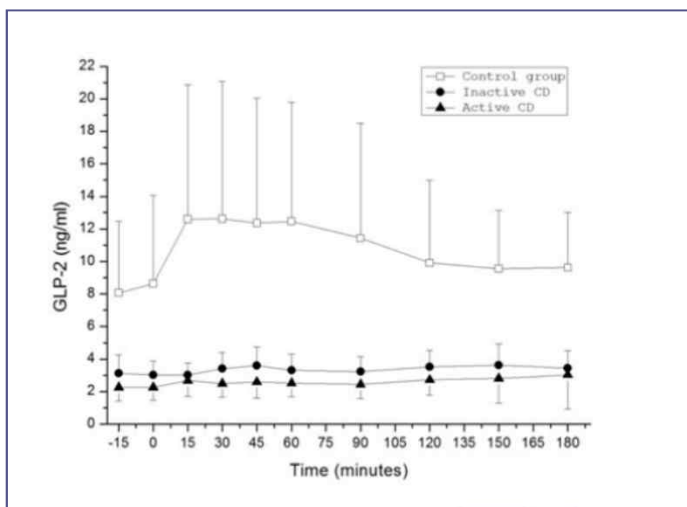
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 의학/학술지 편집인협회, 과학/학술지 편집인협회
 2015년 11월 개정판

중복 출판 발견

2017-A024, 2차 심사 후 리뷰어 제보, 비슷한 topic, 동일한 제 1 저자
The release of glucagon-like peptide 2 is impaired in Crohn's disease

242 The present study has some limitations that must be taken into account. Firstly,
243 it enrolled a small patient population; this occurs primarily due to the high costs
244 of the assays utilized in this study.. Moreover, to measure the markers related
245 to inflammatory status during continuous therapy (mainly biological agents) for
246 CD may have biased the results of some of the molecules that were measured.
247 However, it would be difficult to select patients before treatment and unethical to
248 suspend ongoing treatment regimens for research purposes.



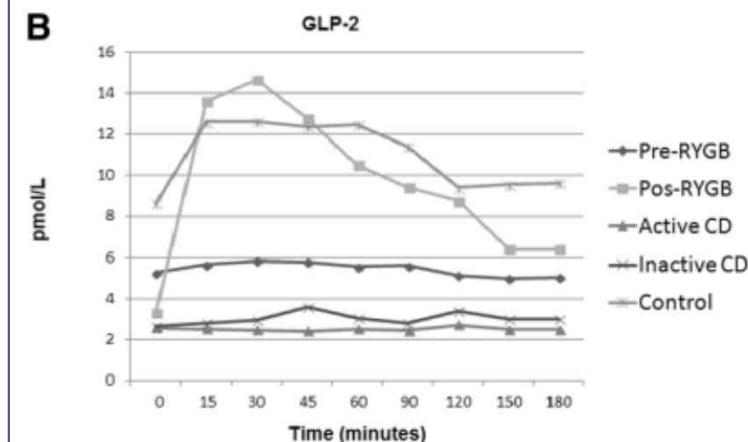
OBES SURG
DOI 10.1007/s11695-017-2851-y



ORIGINAL CONTRIBUTIONS

Glucose Metabolism Parameters and Post-Prandial GLP-1 and GLP-2 Release Largely Vary in Several Distinct Situations: a Controlled Comparison Among Individuals with Crohn's Disease and Individuals with Obesity Before and After Bariatric Surgery

Daniela Oliveira Magro¹ · Everton Cazzo¹ · Paulo Gustavo Kotze² ·
Ana Carolina Junqueira Vasques³ · Carlos Augusto Real Martinez¹ ·
Elinton Adami Chaim¹ · Bruno Geloneze³ · José Carlos Pareja¹ ·
Cláudio Saddy Rodrigues Coy¹



중복 출판에 대한 처리

::: 2nd Review :::			
Editorial Comment EDIT			
Reliance Date	2017-08-18 16:58:30	Response Date	2017-08-18 16:58:30
Recommendation	Reject * English proof reading is required? No		
Comments to the Author	<p>Dear author</p> <p>Thanks for your sincere revision. However, the editorial team finds some ethical problems in your manuscripts.</p> <div style="border: 2px solid red; padding: 5px;"><p>1. Fig 2 of 2017-A024 is identical with Fig. 2B of another paper (Obes Surg 2017). 2. In addition, the patients of CD and control are identical in these two papers. 3. Several sentences of limitation are same in these two papers.</p></div> <p>I assumed that there are some duplication issues in these two papers. Therefore, our editorial team has decided to reject your paper to keep the ethical rule.</p> <ul style="list-style-type: none">Reviewer A : The questions addressed by the reviewers were not well and completely answered. 1. Control (only female), which I think is important, and at least the gender ratio should be matched to the experiment group. 2. The small sample size 3. Why there's no difference between active and inactive group, which might be related to the definition (CDAI only). Would it be possible to have endoscopy or cross section image score? The authors claimed that CRP results were in Table 2. Can you use the combination of CRP and CDAI for the definition and do further analysis? 4. At least you can provide the data and compare the difference between TNF-a Ab users and non-users.Reviewer B : The authors have significantly enhanced the clarity and readability of the manuscript.		
Files	None (or N/A)		

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- 두 학술지 편집인 모두 승인을 하고, 이차 출판 원고를 받은 편집인은 이차 출판물의 복사본이나 재인쇄본을 가지고 있어야 한다.
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이차 출판



STATEMENT

INTESTINAL
RESEARCH

pISSN 1598-9100 • eISSN 2288-1956
<https://doi.org/10.5217/ir.2018.16.2.178>
Intest Res 2018;16(2):178-193

Evidence-based consensus on opportunistic infections in inflammatory bowel disease (republishing)

Inflammatory Bowel Disease Group, Chinese Society of Gastroenterology, Chinese Medical Association

Inflammatory bowel disease (IBD) patients are a high-risk population for opportunistic infections. The IBD group of the Chinese Society of Gastroenterology of the Chinese Medical Association organized an expert group to discuss and develop this consensus opinion. This consensus opinion referenced clinical study results from China and other countries to provide guidance for clinical practices. Eight major topics, including cytomegalovirus infection, Epstein-Barr virus infection, viral hepatitis, bacterial infection, *Mycobacterium tuberculosis* infection, fungal infection, parasitic infection, and vaccines were introduced in this article. (**Intest Res 2018;16:178-193**)

Key Words: Inflammatory bowel disease; Opportunistic infections; Consensus

This article is based on a study first reported in the *Journal of Digestive Disease* 2018;19(2);54-65.

이차 출판



ORIGINAL ARTICLE

INTESTINAL RESEARCH

pISSN 1598-9100 • eISSN 2288-1956
<https://doi.org/10.5217/ir.2017.15.4.475>
Intest Res 2017;15(4):475-486

Efficacy and safety of ustekinumab in Japanese patients with moderately to severely active Crohn's disease: a subpopulation analysis of phase 3 induction and maintenance studies

Toshifumi Hibi¹, Yuya Imai², Yoko Murata², Nobuko Matsushima², Richuan Zheng², Christopher Gasink³

¹Center for Advanced IBD Research and Treatment, Kitasato Institute Hospital, Kitasato University, Tokyo, ²Janssen Pharmaceutical K.K., Tokyo, Japan, ³Janssen Research & Development, LLC, Spring House, PA, USA

Background/Aims: Efficacy and safety of ustekinumab were evaluated in a Japanese subpopulation with moderately to severely active Crohn's disease (CD) in UNIFI-1, UNIFI-2 and IM-UNIFI studies and results were compared with the overall population. **Methods:** Overall, patients in UNIFI-1 (Japan, n=56; failed response to tumor necrosis factor antagonist) and UNIFI-2 (Japan, n=26; failed response to prior conventional therapy) were randomized to placebo or ustekinumab intravenous induction (130 mg or ~6 mg/kg) at week 0. Responders to ustekinumab induction therapy (Japan, n=21) were randomized to placebo or ustekinumab (90 mg, subcutaneous) maintenance (every 12 weeks [q12w] or 8 weeks [q8w]) in IM-UNIFI. The primary end point was clinical response at week 6 for induction studies and clinical remission at week 44 for maintenance study. **Results:** Percentage of patients achieving clinical response at week 6 was greater in ustekinumab 130 mg and ~6 mg/kg groups than in the placebo group (UNIFI-1: 36.8% and 31.6% vs. 27.8%, respectively, for Japanese; 34.3% and 33.7% vs. 21.5%, respectively, for overall; UNIFI-2: 37.5% and 55.6% vs. 11.1%, respectively, for Japanese; 51.7% and 55.5% vs. 28.7%, respectively, for overall). Clinical remission rate at week 44 during maintenance was greater in the ustekinumab 90 mg SC q12w and q8w groups than in the placebo group (50.0% and 55.6% vs. 25.0%, respectively, for Japanese; 48.8% and 53.1% vs. 35.9%, respectively, for overall). Efficacy and safety results observed in the Japanese subpopulation were generally consistent with those in the overall population. **Conclusions:** Ustekinumab could be considered as a new therapeutic option for moderately to severely active CD in Japanese patients. Both ustekinumab induction and maintenance treatments were generally well tolerated (Clinical Trial Registration: NCT01369329, NCT01369342, NCT01369355). (Intest Res 2017;15:475-486)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Ustekinumab as Induction and Maintenance Therapy for Crohn's Disease

B.G. Feagan, W.J. Sandborn, C. Gasink, D. Jacobstein, Y. Lang, J.R. Friedman, M.A. Blank, J. Johanns, L.-L. Gao, Y. Miao, O.J. Adedokun, B.E. Sands, S.B. Hanauer, S. Vermeire, S. Targan, S. Ghosh, W.J. de Villiers, J.-F. Colombel, Z. Tulassay, U. Seidler, B.A. Salzberg, P. Desreumaux, S.D. Lee, E.V. Loftus, Jr., L.A. Dieleman, S. Katz, and P. Rutgeerts, for the UNIFI-IM-UNIFI Study Group*

ABSTRACT

BACKGROUND

Ustekinumab, a monoclonal antibody to the p40 subunit of interleukin-12 and interleukin-23, was evaluated as an intravenous induction therapy in two populations with moderately to severely active Crohn's disease. Ustekinumab was also evaluated as subcutaneous maintenance therapy.

METHODS

We randomly assigned patients to receive a single intravenous dose of ustekinumab (either 130 mg or approximately 6 mg per kilogram of body weight) or placebo in two induction trials. The UNIFI-1 trial included 741 patients who met the criteria for primary or secondary nonresponse to tumor necrosis factor (TNF) antagonists or had unacceptable side effects. The UNIFI-2 trial included 628 patients in whom conventional therapy failed or unacceptable side effects occurred. Patients who completed these induction trials then participated in IM-UNIFI, in which the 397 patients who had a response to ustekinumab were randomly assigned to receive subcutaneous maintenance injections of 90 mg of ustekinumab (either every 8 weeks or every 12 weeks) or placebo. The primary end point for the induction trials was a clinical response at week 6 (defined as a decrease from baseline in the Crohn's Disease Activity Index [CDAI] score of ≥ 100 points or a CDAI score < 150). The primary end point for the maintenance trial was remission at week 44 (CDAI score < 150).

Ref: Manuscript ID: 2016-A045: Efficacy and Safety of Ustekinumab in Japanese Patients with Moderately to Severely Active Crohn's Disease: A Subpopulation Analysis of Phase 3 Induction and Maintenance Studies

Dear Dr. Kim,

We thank the editors and reviewers for their valuable suggestions that we believe have enhanced the scientific value and readability of our manuscript. Point-by-point responses to these comments are provided below. Our revisions, which are highlighted in blue text in the manuscript address each issue raised by the reviewers and editors.

Editor

The Editorial Board decided to recommend that the authors should get a permission from NEJM for publishing subgroup analysis data from its original article. Please submit a permission form as well as your revision. Thank you.

Response: As per the recommendation, we have obtained permission from NEJM for publishing the subgroup analysis data from its original article. The email response from NEJM Licensing & Permissions Specialist and the permission for adapting the panel figures are enclosed below. A footnote mentioning the panel figures "adapted with permission" is also included, wherever applicable.

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동시 출판



SPECIAL REVIEW: Consensus on TB in IBD

INTESTINAL
RESEARCH

pISSN 1598-9100 • eISSN 2288-1956
<https://doi.org/10.5217/ir.2018.16.1.4>
Intest Res 2018;16(1):4-16

Asian Organization for Crohn's and Colitis and Asia Pacific Association of Gastroenterology consensus on tuberculosis infection in patients with inflammatory bowel disease receiving anti-tumor necrosis factor treatment. Part 1: risk assessment

Dong Il Park¹, Tadakazu Hisamatsu², Minhu Chen³, Siew Chien Ng⁴, Choon Jin Ooi⁵, Shu Chen Wei⁶, Rupa Banerjee⁷, Ida Normiha Hilmi⁸, Yoon Tae Jeon⁹, Dong Soo Han¹⁰, Hyo Jong Kim¹¹, Zhihua Ran¹², Kaichun Wu¹³, Jiaming Qian¹⁴, Pin-Jin Hu³, Katsuyoshi Matsuoka¹⁵, Akira Andoh¹⁶, Yasuo Suzuki¹⁷, Kentaro Sugano¹⁸, Mamoru Watanabe¹⁵, Toshifumi Hibi¹⁹, Amarender S. Puri²⁰, Suk-Kyun Yang²¹

Journal of
JGH Gastroenterology
and Hepatology



doi:10.1111/jgh.14019

SOLICITED REVIEW

Asian Organization for Crohn's and Colitis and Asian Pacific Association of Gastroenterology consensus on tuberculosis infection in patients with inflammatory bowel disease receiving anti-tumor necrosis factor treatment. Part 1: Risk assessment

Dong Il Park,* Tadakazu Hisamatsu,[†] Minhu Chen,[‡] Siew Chien Ng,[§] Choon Jin Ooi,[¶] Shu Chen Wei,** Rupa Banerjee,^{††} Ida Normiha Hilmi,^{‡‡} Yoon Tae Jeon,^{§§} Dong Soo Han,^{¶¶} Hyo Jong Kim,^{***} Zhihua Ran,^{†††} Kaichun Wu,^{†††} Jiaming Qian,^{§§§} Pin-Jin Hu,[‡] Katsuyoshi Matsuoka,^{¶¶¶} Akira Andoh,^{****} Yasuo Suzuki,^{††††} Kentaro Sugano,^{††††} Mamoru Watanabe,^{¶¶¶¶} Toshifumi Hibi,^{§§§§} Amarender S Puri,^{¶¶¶¶} and Suk-Kyun Yang^{*****}

*Department of Internal Medicine, Kangbuk Samsung Hospital, Sungkyunkwan University, ^{§§}Department of Internal Medicine, Korea University, ^{***}Department of Internal Medicine, Kyung Hee University, ^{*****}Department of Gastroenterology, University of Ulsan College of Medicine, Asan Medical Center, Seoul, ^{¶¶}Department of Internal Medicine, Hanyang University Guri Hospital, Gyeonggi, Korea, [†]The Third Department of Internal Medicine, Kyorin University School of Medicine, ^{¶¶¶}Department of Gastroenterology and Hepatology, Tokyo Medical and Dental University, ^{††††}Department of Internal Medicine, Toho University, ^{§§§§}Center for Advanced IBD Research and Treatment, Kitasato University, Tokyo, ^{****}Department of Gastroenterology, Shiga University, Otsu, ^{††††}Department of Medicine, Jichi Medical University, Shimotsuke, Japan, [‡]Department of Gastroenterology, The First Affiliated Hospital, Sun Yat-sen University, Guangzhou, ^{†††}Department of Gastroenterology, Shanghai Jiao Tong University, Shanghai, ^{†††}Department of Gastroenterology, Fourth Military Medical University, Xi'an, ^{§§§}Department of Gastroenterology, Peking Union Medical College, Beijing, China; [§]Department of Medicine and Therapeutics, State Key Laboratory of Digestive Disease, Institute of Digestive Disease, LKS Institute of Health Sciences, The Chinese University of Hong Kong, Hong Kong, [¶]Gleneagles Medical Centre and Duke-NUS Medical School, Singapore, ^{**}Department of Internal Medicine, College of Medicine, National Taiwan University Hospital, Taipei, Taiwan, ^{††}Department of Medical Gastroenterology, Asian Institute of Gastroenterology, Hyderabad, ^{¶¶¶¶}Department of Gastroenterology, GB Pant Institute of Postgraduate Medical Education and Research, New Delhi, India, and ^{††}Department of Medicine, University of Malaya, Kuala Lumpur, Malaysia

These consensus were developed and approved by the AOCC and APAGE, and are being published simultaneously in the *Intestinal Research* and *Journal of Gastroenterology and Hepatology*.

텍스트 재활용(text recycling)

- “이미 자신의 저작물에 사용한 문장의 일정 부분을 다시 사용”
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- ‘방법(Methods)’에 대한 기술: 다른 논문에 이미 기술되어 있는지, 적절한 인용 표시를 하였는지 등을 보고 판단
- 종설, 논평, 서신 등 원저가 아닌 문헌에도 동일한 지침을 준수

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2. Methods

2.1. Mice and induction of chronic colitis

Female 6-week-old BALB/c mice obtained from CLEA Japan Inc. (Tokyo, Japan) were maintained under specific pathogen-free conditions. All experiments were approved by the Animal Experimentation Committee of Tokai University, Kanagawa, Japan. Colonic inflammation was induced via intrarectal injection by 3.5-F catheter instillation of a 2% solution of TNBS (Research Organics, Cleveland, OH) in 50% ethanol under light anesthesia with isoflurane. TNBS was provided as 8 weekly injections, with the dose sequentially increasing in the 0.4–1.6 mg range (0.4, 0.4, 0.8, 0.8, 1.2, 1.2, 1.6, and 1.6 mg), as illustrated in Figure 1a. The mice were deprived of food for 24 h before TNBS instillation and were held vertically for 60 seconds after the intrarectal injection. The mice in the ethanol group were given a similar volume of 50% ethanol by intrarectal injection. Tissues and cells were harvested 3 days after the completion of the 8 injections. The colon was opened and snap-frozen for the preparation of frozen sections. In some experiments, formalin-fixed paraffin-embedded sections were prepared for hematoxylin and eosin (H&E) or collagen (Sirius red) staining.

2.2. Administration of PAI-1 inhibitor

TM5275 is a specific inhibitor of PAI-1 molecules, which does not interfere with other serpin/serine protease systems, such as the alpha1-anti trypsin/trypsin and alpha2-antiplasmin/plasmin systems¹².

TM5275 was orally administered as a carboxymethyl cellulose suspension (CMC) each day for two weeks after the sixth TNBS injection. The treatment had no effect on body weight or food intake throughout the experimental duration (data not shown).

2.3. Experimental design

The following groups of mice were included in the present chronic study: 1, Ethanol-treated mice (n = 10); 2, TNBS and carboxymethyl cellulose (CMC)-treated mice (n = 10); 3, TNBS and 10 mg/kg/day TM5275-treated mice (n = 9); 4, TNBS and 50 mg/kg/day TM5275-treated mice (n = 10).

2.4. Histological evaluation and image analysis of colonic fibrosis

An observer blinded to the groups scored the macroscopic colonic lesions. The sum of the scores for colonic lesions, including adhesions, strictures, dilation, thickness, edema, and ulcers, was expressed as the total macroscopic score (the maximum score is 12; Table S1)^{7, 13}.

Specimens obtained from the colons of all mice were washed and immersed in 10% buffered formalin in phosphate-buffered saline overnight at room temperature, followed by the standard procedure for paraffin embedding. Serial 2.5- μ m-thick sections were stained with H&E to assess the degree of inflammation and then with Sirius red to detect tissue fibrosis. An observer, who was unaware of the group assignments, scored all the histological sections of the colonic samples based on the presence of ulcerations, the degree of inflammation, the depth of the lesions, and the degree of fibrosis. The degree of intestinal inflammation was scored as absent, mild, moderate, or severe according to the density and extent of acute and chronic inflammatory infiltrates, loss of goblet cells, and thickening of the bowel wall. Intestinal fibrosis was scored as absent, mild, or severe, depending on the density and extent of connective tissue staining and the disruption of tissue architecture (the maximum microscopic score is 10; Table S1)¹⁴.

Inhibition of plasminogen activator inhibitor-1 protects against intestinal fibrosis in mice

ORIGINALITY REPORT

44%

SIMILARITY INDEX

PRIMARY SOURCES

- 1 Jin Imai, Katsuto Hozumi, Hideaki Sumiyoshi, Masaki Yazawa et al. "Anti-fibrotic effects of a novel small compound on the regulation of cytokine production in a mouse model of colorectal fibrosis", *Biochemical and Biophysical Research Communications*, 2015
762 words — 29%
Crossref
- 2 Hiroko Nagao-Kitamoto, Andrew B. Shreiner, Merritt G. Gilliland, Sho Kitamoto et al. "Functional Characterization of Inflammatory Bowel Disease-Associated Gut Dysbiosis in Gnotobiotic Mice", *Cellular and Molecular Gastroenterology and Hepatology*, 2016
74 words — 3%
Crossref
- 3 Florian Rieder, Dominik Bettenworth, Jin Imai, Yutaka Inagaki. "Intestinal Fibrosis and Liver Fibrosis:
58 words — 2%

해석

1. 방법이 저자가 이전에 작성한 논문과 거의 동일
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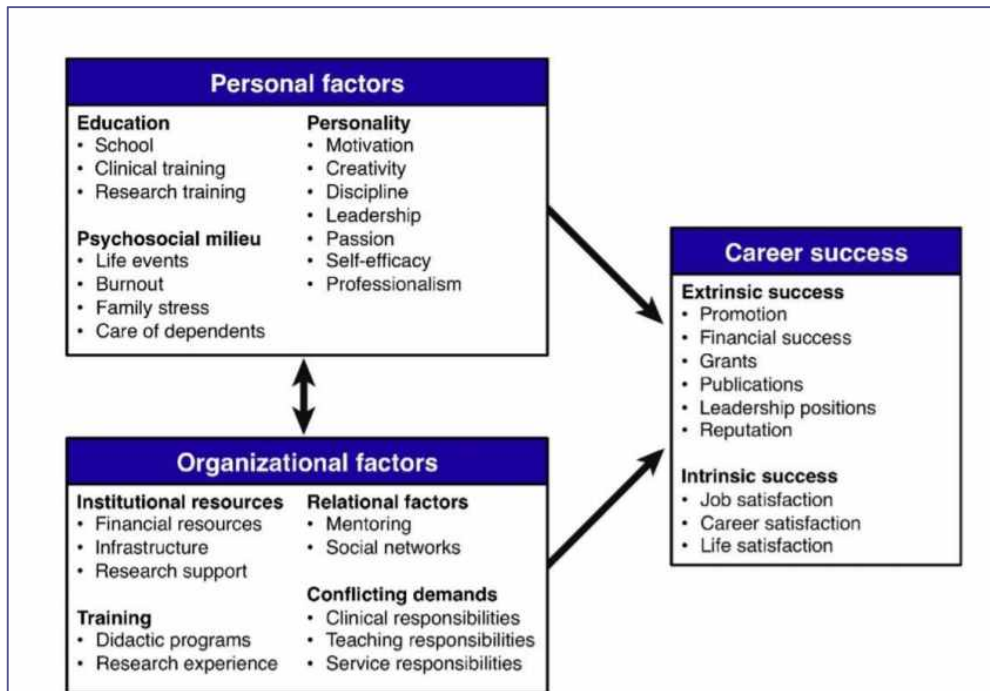


Fig. Fig. Personal and organizational factors can contribute to the success of new faculty.(adapted from Mehta et al15)



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INTESTINAL RESEARCH

Posted in January, 2019

PRINCIPLES OF TRANSPARENCY AND BEST PRACTICE

1. Website

The URL address of official web site is <http://www.irjournal.org>.

1) 'Aims & Scope' statement

The aim of the Journal is to provide broad and in-depth analysis of intestinal diseases, especially inflammatory bowel disease, which shows increasing tendency and significance. As a Journal specialized in clinical and translational research in gastroenterology, it encompasses multiple aspects of diseases originated from the small and large intestines. The Journal also seeks to propagate and exchange useful innovations, both in ideas and in practice, within the research community. As a mode of scholarly communication, it encourages scientific investigation through the rigorous peer review system and constitutes a qualified and continual platform for sharing studies of researchers and practitioners. Specifically, the Journal presents up-to-date coverage of medical researches on the physiology, epidemiology, pathophysiology, clinical presentations, and therapeutic interventions of the intestinal diseases. General topics of interest include inflammatory bowel disease, colon and small intestine cancer or polyp, endoscopy, irritable bowel syndrome and other motility disorders, infectious en-

teric and translational research in gastroenterology. Clinicians in the field can get up-to-date information and recent development of medical researches on the physiology, epidemiology, pathophysiology, clinical presentations, and therapeutic interventions of the intestinal diseases. Professors can access and adopt a variety of data in medical education. Allied health professionals including nurses are able to get the recent information for care of patients with gastrointestinal diseases. Medical students can understand the recent trends of the field and interesting cases for their work. Policy makers are able to reflect the results of the articles to the nation-wide science promotion policies.

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Authorship credit should be based on: 1) substantial contributions to conception and design, acquisition of data, and/or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; 3) final approval of the version to be published; and 4) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Every author should meet all of these four conditions. After the initial

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5) pISSN: 1590-9100; eISSN: 2280-1956

2. Name of journal

The official journal title is *Intestinal Research*. Abbreviated title is *Intest Res*.

3. Peer review process

http://www.irjournal.org/authors/peer_review.php

The peer review afterward is conducted through the system as well. All manuscripts undergo peer review by at least three reviewers with relevant expertise who are selected by the editorial board. The decision to publish will be made by the editor-

in-chief. The decision to publish will be made by the editor-in-chief. The decision to publish will be made by the editor-in-chief. The decision to publish will be made by the editor-in-chief. Rejected manuscripts are not to be considered again.

4. Ownership and management

1) Information about the ownership

This journal is owned by the academic society, Korean Association for the Study of Intestinal Diseases <http://www.gat.or.kr>.

2) Management team of a journal

- Journal management team (2017-2019)
- Journal Manager: Yui Sun Kim, Inje University of Seoul, Korea, Deputy Editors of Intestinal Research
- Manager of the Review Process: Jae Hee Cheon, Yonsei University of Seoul, Korea, Associate Editor of Intestinal Research
- Ethics Editor: Ji Won Kim, Seoul National University of Seoul, Korea, Associate Editor of Intestinal Research
- Statistics Editor: Inkyung Jung, Yonsei University of Seoul, Korea
- Manuscript Editors: Mi Young Park, Infruhmi, Korea
- Layout Editors: Hyeon Jung Park, Academya, Korea
- Website and JATS XML File Producers: Younsang Cho, M2community, Korea

5. Governing body

The governing body is the journal's editorial board.

6. Editorial team and contact information

<http://www.irjournal.org/about/editorial.php>

Editor-in-Chief

Toshikuni Hibi, *Kioto Univ., Japan*

학술지 논문 출판시 환자의 개인정보 보호에 관한 권고안 제정

최근 ICMJE와 많은 학술지에서 환자의 개인정보를 보호하려는 시도가 강화되면서 일부 학술지에서는 이미 관련 내용을 투고규정에 포함 또는 개정하고 있다. 출판윤리의 저변확대를 위해 의학학술지편집인협회 출판윤리위원회에서는 각 회원 학술지 편집인에게 출판물에 불필요한 환자의 개인정보가 드러나지 않도록 개인정보 보호와 관련된 투고규정의 개정을 포함한 윤리적, 제도적 장치를 보완해 줄 것을 요청한다. 환자는 사생활을 보호받을 권리가 있으며, 개인정보는 반드시 필요한 경우가 아니면 공개해서는 안 된다. 출판물에 환자의 이름, 이름의 머리글자, 병록번호, 사진, 가계 등 식별 가능한 정보는 어느 형태로든 출판할 수 없다. 불필요한 환자의 세부개인정보는 가능한 생략한다. 단, 과학정보로서 환자의 개인정보 노출이 필수불가결한 경우에는 출판 전 환자 또는 환자의 법정대리인에게 이를 설명하고, 서면으로 동의서를 취득해야 한다. 또한 이때 환자의 개인정보가 출판물뿐만 아니라, 인터넷 등을 통해 공개될 가능성이 있음을 고지해야 한다. 학술지 편집인은 대상자 동의서 취득을 포함한 환자의 개인정보 보호 관련 규정을 반드시 학술지 투고규정에 포함시키고, 게재 논문에도 정보에 입각한 환자(또는 법정대리인)의 자발적 서면 동의 취득을 표시해야 한다. 학술지 편집인은 개별적 관련 규정에 따라 취득한 서면 동의서를 보관하거나 혹은 보관과정에서 환자의 개인정보 식별이 우려되는 경우 저자가 서면 동의서를 보관하도록 하고, 대신 동의서를 규정에 따라 취득하여 보관하고 있음을 증명하는 내용을 논문에 표시하도록 한다. 한편, 환자의 익명성을 유지하기 위한 보호 과정에서 편집인은 원 자료의 과학적 의미를 왜곡시키지 않도록 주의해야 한다. 즉, 학술지는 사례발표를 포함한 사람을 대상으로 하는 연구를 보고할 때는 대상자(환자) 동의서와 관련된 규정을 투고규정에 반드시 포함시켜야 하며, 대상자 동의서를 취득한 경우에는 게재하는 논문에 이를 적시하여야 한다.

2017.11.30.

의학학술지편집인협회 출판윤리위원회

학술논문 작성 시 저자가 알아야 할 투명성을 이해하였는가?

- 저자됨
- 이해관계 (Conflict of Interest: COI)
- 표절
- 중복출판, Text recycling
- 저작권
- Best practice

- 2008년 의학논문 출판윤리 가이드라인
- 2013년 의학논문 출판윤리 가이드라인 제2판
- 2014년 출판윤리 가이드라인 : Q&A 사례분석
- 2019년 의학논문 출판윤리 가이드라인 제3판

