

### Disclosure

- Conflict of Interest: None
- Research Grant for Korean National Cancer center, Ministry for health, welfare affairs, consultant for Schering-Plough, Investigator of the Millennium trial for IBD.

## Agenda

- 용어설명
- 편집인
- 심사자
- 원고 확인요소
- 통일양식(Uniform Requirement for Manuscripts Submitted to Biomedical Journals)

### 용어 해설

- 편집인: 해당 학술지에 대해 책임지는 사람
- 심사자: 원고를 평가하여 과학으로 승화
- 발행인: 학술지 발행 비용의 책임자
- 인쇄인:인쇄와 제본을 책임지는 사람
- Manuscript editor:

## 편집인의 책임

- 학술지 질에 대한 책임
- 공정한 평가
- 윤리 기준
- 질관리

### 학술지 질의 유지

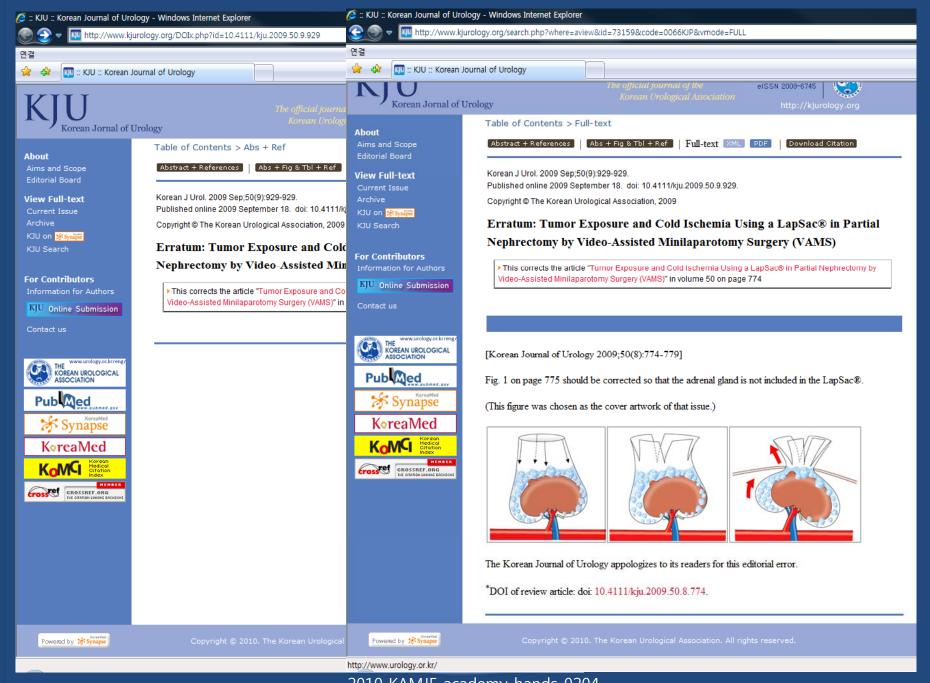
- 임상 및 과학관련 연구 보고를 향상시키기 위함
- Correct, valid, reliable
- 학술지의 목표와 범위를 따라야 함
- 내용에 대한 기준
  - "Is it true?", "Is it new?", "Will affect patient care?" -by Sox HC, ex-editor, Annal Intern Med.
- 교육자의 역할: 저자됨, 이해관계, 윤리를 교육

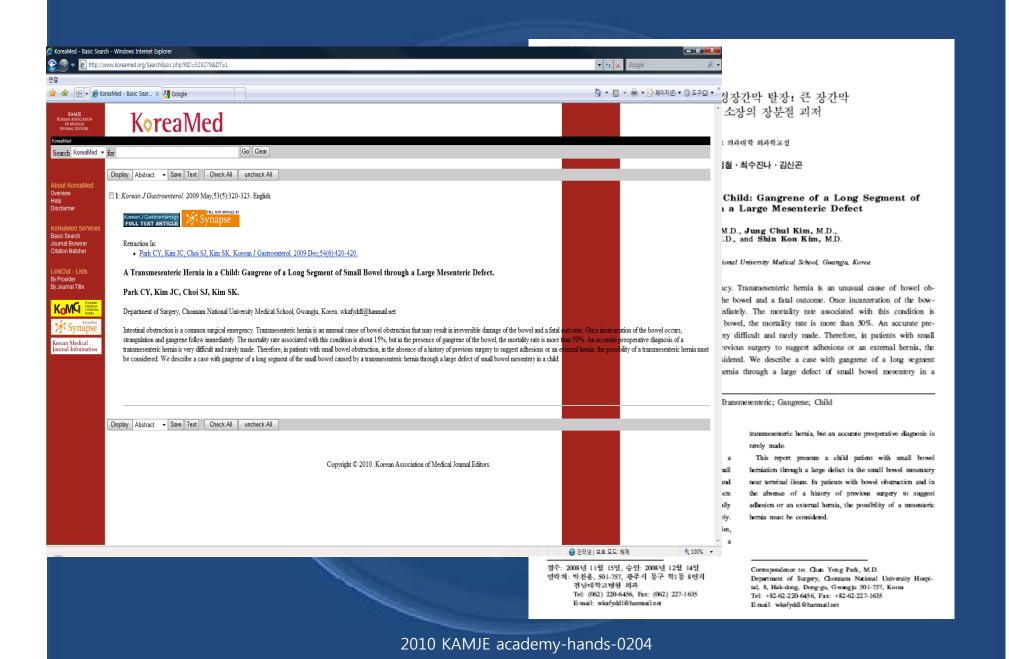
### 편집방침

- 학술지의 목표와 범위에 맞게 수행
- 사전에 편집 규정, 투고규정을 명문화
- 저자에 대한 방침
- 독자에 대한 방침

### 질관리

- 정정(Correction) or 오류(erratum)
- 논문취소(Retraction)
- Monitor peer review: review reviewers, process analysis





## Reviewing the Reviewers: Comparison of review quality and reviewer characteristic at the American Journal of Roentgenology

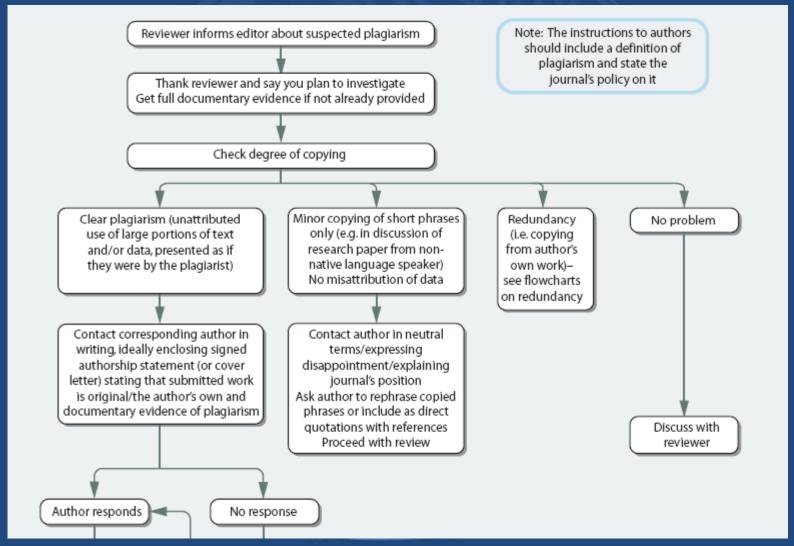
- Rank by journal editors by 4 scales
- Characteristic from 989 reviewersor erratum
- Quality scores correlate with younger age (p=0.001), practice type(p=0.008)
- No significant relationship with sex(0.72), year of reviewing(p=0.26), academic rank(p=0.1), and subspecialty(0.99)

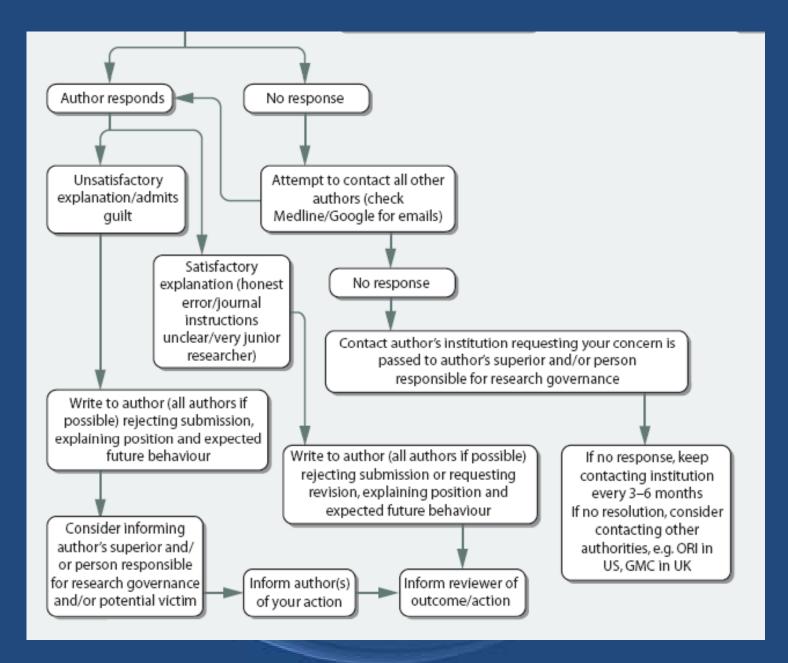
	총심사 건수	2차 심사수	총심사 기간(일)	평균심사 기간(일)	편당심사 기간(일)	심사근거
1	2	2	115	38.3	28.7	39, 63
2	2		11	5.5		78, 91
3	3	2	70	23.3	7.2	18, 36, 78
4	1	1	31	31	15.5	20
5	3	3	86	28.6	12	25, 42, 81
6	3	3	140	46.6	17.6	30, 34, 53
7	3	3	45	15	7.5	15, 68, 89
8	5	5	216	43.2	16.8	3, 19, 23, 48, 54
9	3		56	18.6		16, 41, 47
10	4	1	93	23	17.5	8, 38, 51, 57
11	6	4	83	13.8	6.5	21,31,55,57,66,67
12	3	3	262	87	34.2	14, 37, 40
13	3	3	80	26.6	13.3	2, 29, 62
14	2	2	51	25.5	12.7	7, 50
15	1	1	49			
16	5	4	104	20.8	10.7	12, 26, 58, 66, 73
17	2	2	99	49.5	19.5	5, 56
18	1					
19	3	3	130	43.3	19.5	22, 33, 65
20	3	2	71	23.6	12	45, 76, 97
21	2	2	54	27	13.5	75, 93
22	4	4	105	26	8.7	9, 21, 24, 52
23	6	5	210	35	16.6	6,34,46,50,60,67

### 편집인의 자세

- 저자를 존중하고, 예의와 권위를 갖춤
- 독자에게 흥미를 유발하고 최신정보 제공
- 전문가심사자의 권위를 부여하고 공정하게
- 연구/출판 윤리 위반이 없도록 조치

## 표절이 의심될 때



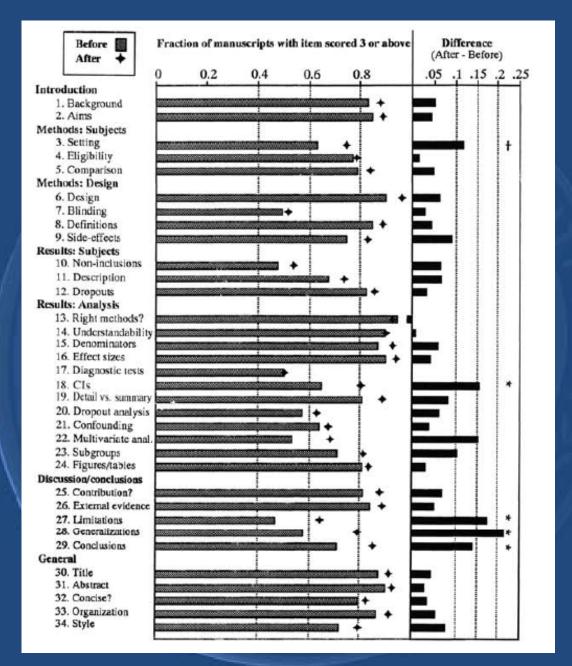


### 심사의 목적

- 논문 질을 판단-오류유무 확인
- 제시된 결과의 결론 일치여부
- 과거 업적에 대한 인용의 적절함
- 적절한 기관의 기준에 따른 윤리 문제
- 원저이고 중요성 판단

### Conventional Peer Review

- One to three reviewers per manuscript
- Reviewers selected from database, organised by expertised
- Reviewers are not required to sign their reviews
- A time dealine for returning reviews
- Authors do not know reviewers' names and institutions
- Simple, general instructions to reviewers
- As reviewers to provide: Comments for authors, comments for editors, drage on individual components and overall quality of the manuscript
- Reviewers are not paid for their work



### 심사자의 자세

- 독자의 입장에서 논문을 검토
- 학술지의 학문적 정보 전달에 도움
- 건설적이고 도움이 되는 비평
- 등재여부 결정에 필요한 의견이나 근거를 제시
- 윤리적이고 중립적일 것
- 투고 결과내용을 보장
- 기한 내에 심사할 것
- 중복출판, 표절을 지적

### 원고심사법

- 1. 심사수용
- 2. 일차 읽기
- 3. 이차 읽기
- 4. 의견서 작성
- 5. Down to Earth Method

Hoppin FG. Am J Respir Crit Care Med 2002

### **Reviewer: 1 Comments to the Author**

Remarks to the author: I agree with your belief that your study is a good addition to the literature on FITs but I think you haven't sufficiently acknowledged the work of others before yo u and you need to do so. Some of your references would benefit from updating and a couple of the sentences in your Discussion look like almost direct copies of similar discussion points in other published literature. This needs to be acknowledged.

### Abstract

- 1..Background 1st sentence Using the strictest criteria this sentence may be accurate but, there are a number of studies in the literature dating back to the 1990's (some of which you have cited) comparing fecal immunochemical tests (FITs) to standard and sensitive guaiac tests in average risk populations that have shown FIT superiority. What is unique about your st udy is the colonoscopies done on all the participants whether or not they had a positive test. A similar study which you do not reference did look at FIT vs. GT in a large average risk population with all negatives having flexible sigmoidoscopy. (Allison JE, Sakoda LC, Levin TR, Tucker JP, Tekawa IS, Cuff T, Pauly M, Shlager L, Palitz A, Zhao WK, Schwartz JS, Ransohoff D, S elby J Screening for Colorectal Neoplasms With New Fecal Occult Blood Tests: Update on Performance Characteristics J Natl Cancer Inst 2007;99: 1 9) It would be interesting to compare your results with this one as it only has gold standard endoscopic follow up for left sided ACRNs and used a different FIT.
- 2. In the U.S. the term FIT is used more commonly than iFOBT for fecal immunochemical test and I suggest you use this term throughout your manuscript.
- 3. The second sentence isn't clear. What do you mean by determining the number of iFOBTs needed? I think you mean the number of FITs needed to perform on a patient to get the be st sensitivity and specificity. If so, say that.
- 4. It is important for you to define the term ACRN and advanced adenoma for your study here. In the body of the manuscript you explain ACRN is both cancer and advanced adenomas and you define advanced adenoma. I believe it is preferable to present the performance characteristics of your FIT for cancer, advanced adenomas, and both i.e. ACRNs.

### Introduction

- 1. Second paragraph first sentence It is incorrect to say the gFOBT has been criticized for poor specificity. The standard gFOBT, Hemoccult II, has very good specificity. It is the Hemoccult Sensa or sensitive quaiac test that in some studies has shown very poor specificity.
- 2. You use a lot of old references such as references 6-8 and 11-14. There are better references with data on the performance characteristics of gFOBTs such as the following:
- a. Ahlquist DA, Sargent DJ, Loprinzi CL, Levin TR, Rex DK, Ahnen DJ; Knigge K Lance MP, Burgart LJ, Hamilton SR; Allison JE, Lawson MJ, Devens ME; Harrington JJ; and Hillman SL Stool DNA versus Occult Blood Testing Stool DNA and Occult Blood Testing for Screen Detection of Colorectal Neoplasia: A Prospective Multicenter Comparison Ann Intern Med. 2008;149:441

  -450
- b. Imperiale TF, Ransohoff DF, Itzkowitz SH, et al. Fecal DNA versus fecal occult blood for colorectal-cancer screening in an average-risk population. N Engl J Med 2004; 351:2704–2714 c. Allison JE The Role of Fecal Occult Blood Testing in Screening for Colorectal Cancer Practical Gastroenterology June 2007 Vol. XXXI; 20-32.
- 3. P. 4 first paragraph second sentence I agree with your statement about office development but, can you reference a publication where it has actually been shown that there is a problem with maintaining quality control for office development of FITs? I think unless you can this statement is your opinion and not fact. It also looks very much like an advertisement for the FIT your funder markets.

### Methods

- 1. P. 6 first paragraph You decided upon not having dietary restrictions. Do you think this could be the reason for your unusually high positive rate for Hemoccult II? Furthermore the use of vitamin C could account for some false negatives in this group making FIT look better.
- 2. I don't think that diminutive polyps found on investigation of a positive gFOBT or FIT were the cause of the positive test and, therefore; shouldn't be counted when determining sensitivity and specificity of a screening test. Even the majority of those adenomas 5mm to 9mm found during an evaluation of a positive test are unlikely the cause of the positive test. Read Ransohoff DL Lang CA Small adenomas detected during fecal occult blood test screening for colorectal cancer. The impact of serendipity. JAMA. 1990 Jul 4; 264(1):76-8.
- 3. P.8. first paragraph Here you define the term advanced adenoma and ACRN. It is more useful to the reader if you present your results as cancer, advanced adenomas and ACRN rat her than just advanced adenoma and ACRN. In general readers want to know the sensitivity of the screening test for cancer, advanced adenoma, and both.

### Role of the Funding Source

1. Did the funding source read the manuscript and did you use any of its suggestions for manuscript wording or content?

### Results

1. Patients and Colonoscopy Results – As mentioned previously, I think reporting the number of diminutive polyps is of no value and even the number of polyps between 5 -9 mm may not be important. The most important findings to talk about are the advanced adenomas and cancers. In most large screening programs the number of cancers found is roughly 1-3 in a thousand. In your study there was roughly 1 in 100. Can you speculate as to why there were so many in your study population? P erhaps it is because the study population is from tertiary medical centers. Table 1 has too much information and is difficult to read. I suggest it be simplified by taking out some categories and making it into two Tables.

### **FOBT Results**

- 1. You need to better explain how you determined the Hemoglobin level in your gFOBTs or did you? I also don't understand what you did with the 3 FITs to represent the m as one test. Do you mean that the test was considered positive at any hemoglobin level up to a threshold of 100 ng/ml? You need to be more clear here. A posi tivity rate of 7.9% is very high for a standard guaiac test and looks more like the result for a sensitive guaiac test or a rehydrated guaiac test. The positivity rate for the FIT at both a threshold of 75 ng/ml and 100ng/ml are also high compared to other FITS and even some results reported for the same FIT you used. Perhaps the latter is related to number of tests performed on each patient or, as you state in the discussion section, your study population comes from tertiary medical centers. Please comment on both of these findings. They have importance when considering FITs for population screening as each positive test requires colonoscopy follow up. It would be helpful if you calculated a positive predictive value for both your gFOBT and your FIT both for cancer and advanced adenomas so comparisons could be made with data on other FITs and gFOBTs.
- 2. Performance Comparison between gFOBT and qiFOBT at the Various Hemoglobin Thresholds In Table 2, is the number of patients with true negative results for a Hgb threshold of 125 ng/ml is 291 or is that a misprint? Perhaps it is actually 691. If not please explain.
- 3. P.12 paragraph 2 last sentence I think you mean the fecal hemoglobin cut off value that gives the best sensitivity and specificity for cancer is 118ng/ml.
- 4. The number of qiFOBTs Needed to Identify ACRN What you are saying under this heading needs better explanation because looking at Table 3 gives me the impression that 2 specimens give the best sensitivity and specificity for cancer but for ACRN, the majority of which are advanced adenomas, 3 tests seem to give the best per formance characteristics. If I am interpreting this correctly, the number of tests one would select could differ depending on your screening goal: the most cancers or the most cancers and advanced adenomas. Given limited colonoscopy resources, some screening programs would choose the test with the least number of specime ns needed to detect the most cancers and assume the missed advanced adenomas would be uncovered in subsequent screens.

### Discussion

- 1. P.13,14 first paragraph sentences 2,3 Sentence 2 is technically correct regarding the study cited but ignores a subsequent study by the same group using flexible sigmo idoscopy for FIT negative subjects. Allison JE, Sakoda LC, Levin TR, et al. Screening for colorectal neoplasms with new fecal occult blood tests: update on performanc e characteristics. J Natl Cancer Inst 2007;99:1–9. Sentence 3 ignores a large Japanese study where all average risk patients were given a FIT and subsequently colono scoped. Morikawa T, Kato J, Yamaji Y, et al. A comparison of the immunochemical fecal occult blood test and total colonoscopy in the asymptomatic population. Gas troenterology 2005; 129:422–8.
- 2. P. 15 first paragraph second to last sentence. I think the Japanese study you cite here is the one I have listed above but you don't reference it in your bibliography.
- 3. P. 16 first paragraph The two sentences beginning with "Advanced adenoma consists" are very similar to ones in a published manuscript on FOBTs. The source should be referenced.

## 심사자의 논문 판단 조건

- timely and relevant to a current topics
- well written, logical, and easy to comprehend
- well designed and appropriate methodology

### 심사자가 답변 작성전 고려할 것

- 연구 배경의 중요함
- 원저
- 결과에서 방법, 실험방법, 통계방법, 해석의 장단점
- 서술 스타일과 적절한 그림, 테이블제시
- 윤리문제 (동물, 사람)

## 편집인이 판단하는 심사의 질

- 심사를 철저하고 이해하는 수준인 지?
- 시간의 적절함
- 저자에게 제시하는 적절한 근거를 가진 내용
- 건설적인 비평
- 객관성
- 원고 출판 여부에 대해서 편집자에게 명쾌한 설 명

### Peer Review의 효율성 올리기

- 좋은 reviewer선정
- Reviewer 수
- Reviewer 교육
  - 일임
  - Checklist
  - 상대방 reviewer글
- Blind reviewer

# 논문의 구성요소

• Abstract(초록)

• Introduction(서론)

• Method(방법)

• Results(결과)

• Discussion(고찰)

# 초록의 형식

### Genetic

- Background
- Objective
- Methods
- Results
- Conclusions

### **JAMA**

- Context
- Objective
- Design
- Setting
- Patients
- Interventions
- Main outcome measures
- Results
- Conclusions
- Trial registration

## 초록

- 초록은 원고와 독립적이다
- 초록 만으로 전체를 이해할 수 있도록
- 연구목표, 수치 오류를 확인

## 서론

- 연구 타당성을 제공
- 연구 목표를 설명
- 적절한 문헌을 간략하게 제시

### 방법

- 짧고 간결하게 처음에는 개관을 기술
- 신뢰성의 척도
- 치밀하게 기술(예; 시간, 실험방법, 목표)
- 특이한 경우는 상세하게, 흔한 것은 이전 것을 인용

### 결과

- 관찰한 것을 기록
- 해석은 고찰에서
- 표, 그림에 결과를 반복하지 않는다.
- 짧은 문장으로 단순, 명료하게 기술
- 결과와 방법, 목적을 연결

### 고찰

- 자신이 제기한 가설이 결과를 통해 옳은 지 분석하는 부분
- 발견된 사실에 대한 충분한 토론
- 교과서 나열을 피함
- 예상치 못한 결과의 분석
- 연구 제한점 분석

### Treatment with Monoclonal Antibodies against Clostridium difficile Toxins

Israel Lowy, M.D., Ph.D., Deborah C. Molrine, M.D., M.P.H., Brett A. Leav, M.D., Barbra M. Blair, M.D., Roger Baxter, M.D., Dale N. Gerding, M.D., Geoffrey Nichol, M.B., Ch.B., William D. Thomas, Jr., Ph.D., Mark Leney, Ph.D., Susan Sloan, Ph.D., Catherine A. Hay, Ph.D., and Donna M. Ambrosino, M.D.

#### BACKGROUND

New therapies are needed to manage the increasing of recurrence of Clostridium difficile infection.

#### METHODS

We performed a randomized, double-blind, placel tralizing, fully human monoclonal antibodies again a dose of 10 mg per kilogram of body weight, in pat infection who were receiving either metronidazole come was laboratory-documented recurrence of in the administration of monoclonal antibodies or pla

### RESULTS

Among the 200 patients who were enrolled (101 in t placebo group), the rate of recurrence of C. difficile tients treated with monoclonal antibodies (7% vs. 7 to 29; P<0.001). The recurrence rates among patient strain were 8% for the antibody group and 32% f among patients with more than one previous episc tial hospitalization for inpatients did not differ sig and placebo groups (9.5 and 9.4 days, respectively). A was reported by 18 patients in the antibody group a group (P=0.09).

#### CONCLUSIONS

The addition of monoclonal antibodies against C. d. ber, NCT00350298.)

the antibody group and 28 patients in the placebo group (P=0.09).

The proportions of patients with the most frequent grade 3 or 4 adverse events were similar in the two study groups, except for significantly fewer reports of hypotension in the antibody group (Table 3). Analysis of adverse events during the overall study period revealed several nonseri-B (CDE1). The antibodies were administered toget ous adverse events (including anorexia, anxiety, diarrhea, depression, and insomnia) that were significantly less common in the antibody group than in the placebo group (Table 3 in the Supplementary Appendix).

To examine the immunogenicity of the monoclonal antibodies, human antihuman antibody titers in response to CDA1 and CDE1 were assessed before and after study infusion at multiple time points. Two patients in the antibody group had rence rates were 7% and 38%, respectively (P=0.00) a positive titer before infusion; one of these patients had no detectable titer after infusion, and the other patient's titer was unchanged after infusion. In 20 patients (8 in the antibody group and 12 in the placebo group) who were followed for 6 months (last assessment, day 168 plus or minus significantly reduced the recurrence of C. difficile in: 14) after infusion, human antihuman antibody titers were not detected.

### DISCUSSION

In our study, the administration of fully human monoclonal antibodies favorably affected the natural history of C. difficile infection when added to treatment with metronidazole or vancomycin. A single infusion of two monoclonal antibodies against C. difficile toxins A and E (CDA1 and CDE1) resulted in a reduction of the rate of recurrent infection among patients treated with standardof-care antibiotics. Although the primary end point of the study was a reduction in the rate of recurrence, secondary end points evaluated the effect of monoclonal-antibody treatment on the initial episode of infection. The time to the resolution of diarrhea, number of days of hospitalization for the initial episode, and severity of diarrhea during the initial episode were similar in the two study groups. CDA1 and CDB1 are fully human antibodies, each of which targets an exogenous antigen. Immunogenicity was not detected in any patient during the study period.

Larger studies will need to be conducted to confirm the findings of this phase 2 study. Our results are consistent with those of previous studies that correlated serum levels of antitoxin an-

### 그림, 그래프, 표

- 방법이나 결과 중 중요한 것을 표시
- 그림 설명은 본문을 읽지 않고도 이해가 되도록
- 독자의 이해가 쉽도록
- 적절한 화살표를 표시
- 적절한 수의 표, 표와 본문이 중복되지 않도록

## 참고문헌

- 전체 원고의 질을 반영
- 정확한 인용
- 정확한 표기
- 불필요한 인용 피할 것

## 보조 자료

- 참고자료 (references)
- 주석 (Note or footnotes)
- Figure legends (각각 다른 쪽 표시)
- Figures
- Tables
- Image or other illustrations
- Supplementary material

### ICMJE Uniform Requirements

연구 수행과 출판에 있어 윤리

- 저자됨(Authorship)
- 편집과 편집권(Editorship)
- 동료에 의한 전문가심사(Peer review)
- 이해관계(Conflict of interest)
- 사생활과 비밀보호(Patient confidentiality)
- 연구 대상 사람과 동물의 보호(Human and animal subjects)

Source: ICMJE, http://www.icmie.org

### 의학학술지 출간과 관련된 출판 및 편집

- 네거티브 연구결과를 출판할 의무(Publication of negative results)
- 정정, 철회, 우려 표명
- 저작권
- 중복출판(Overlapping publication)
- 교신 및 독자투고(correspondence)
- 별호, 증보판, 특별출판물
- 전자출판
- 광고
- 의학학술지와 언론매체
- 임상시험 등록의무

### 편집인의 독립

- "편집인이 학술지 편집내용과 관련된 완전한 독립권한을 가지는 것"
- 의학적 소신을 지킬 의무
- Canadian Medical Association Journal

### CMAJ event

- 2006년 2월: 10년간 근무한 editor-in-chief, editor 해고
- 이후 편집관련 종사자 동반사직
- Lancet: "sacking of CMAJ editors is deeply troubling."
- New England Journal of Medicine: "The Collapse of the Can adian Medical Association Journal."
- Science: "Turmoil Threatens to Sink Canadian Journal."
- 출판내용에 대한 소속 학회 방침과 불일치 (2001, 2002, 2005)
- 학술지 편집권 독립과 발행인과의 관계에 대한 숙제

# 현행 학술지 발행의 문제점

Annal Intern Med	국내 학술지
고비용 발행구조	SCI우선정책
학술지 발행 비용 확보	학문의 세분화
학문의 세분화	
Web-based media	
경제상황	

## 유용한 싸이트

www.kamje.or.kr

www.wame.org

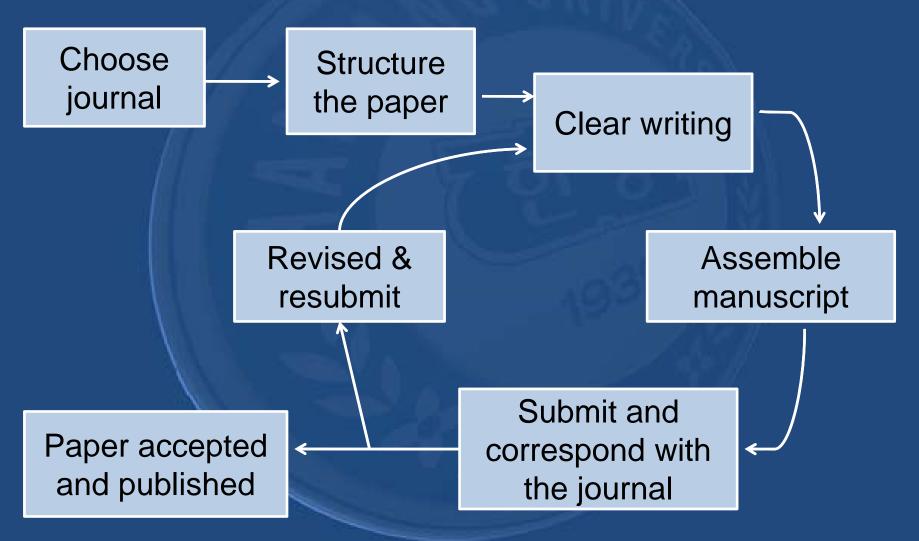
www.pulicationethics.org.uk

Lancet, New England Journal of Medicine,
 JAMA, Annals of Internal Medicine

## 심사제도의 보완책

- 우수심사자 발굴
- 교육프로그램
- 심사상황에 대한 피드백
- 적절한 보상
- 외부 인력의 활용
- 외부 모니터링

## 원고 투고절차



2010 KAMJE academy-hands-0204

