Journal of Biomedical Research

Bo Cui, MD/PhD

Executive Editor

March 9, 2014

Xian, Shaanxi

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Effective Writing for Biomedical Publications

- Secondary data utilization
- How to respond to reviewer critique

Figure 1.4. **Top 20 publishing cities 2004–2008, and their growth since 1996–2000.**[126]

Knowledge, Networks and Nations: Global scientific collaboration in the 21st century

RS Policy document 03/11
Issued: March 2011 DES2096

ISBN: 978-0-85403-890-9

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Effective Writing for Biomedical Publications

- Secondary data utilization
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Secondary data utilization

- Editorial
- Original article
- Review article
- Short paper
- Case report
- Letter to the editor
- Personal views
- Special communications

- It is a scientific report of the results of *original* basic or clinical research.

Secondary data utilization

- Original :

  1) of, relating to, or constituting an origin or beginning;

  2) not secondary, derivative, or imitative;

  3) being the first instance or source from which a copy, reproduction, or translation is or can be made;

  4) independent and creative in thought or action .

Merriam Webster Dictionary

Secondary data utilization

- Previous research studies: collect more data than PI can analyze and some interesting findings go unnoticed.
- -Large regional and national data sets
- Tumor registries
- Administrative and clinical databases: useful for studies to evaluate patterns of utilization and clinical outcomes of medical treatment

JAMA The Journal of the American Medical Association

August 19, 1998, Vol 280, No. 7 >

The Heart and Estrogen/progestin Replacement Study (HERS)

Original Contribution | August 19, 1998

Randomized Trial of Estrogen Plus Progestin for Secondary Prevention of Coronary Heart Disease in Postmenopausal Women FREE

Stephen Hulley, MD; Deborah Grady, MD; Trudy Bush, PhD; Curt Furberg, MD, PhD; David Herrington, MD; Betty Riggs, MD; Eric Vittinghoff, PhD;

JAMA. 1998;280(7):605-613. doi:10.1001/jama.280.7.605.

ABSTRACT

The Heart and Estrogen/progestin Replacement Study (HERS)

Background:

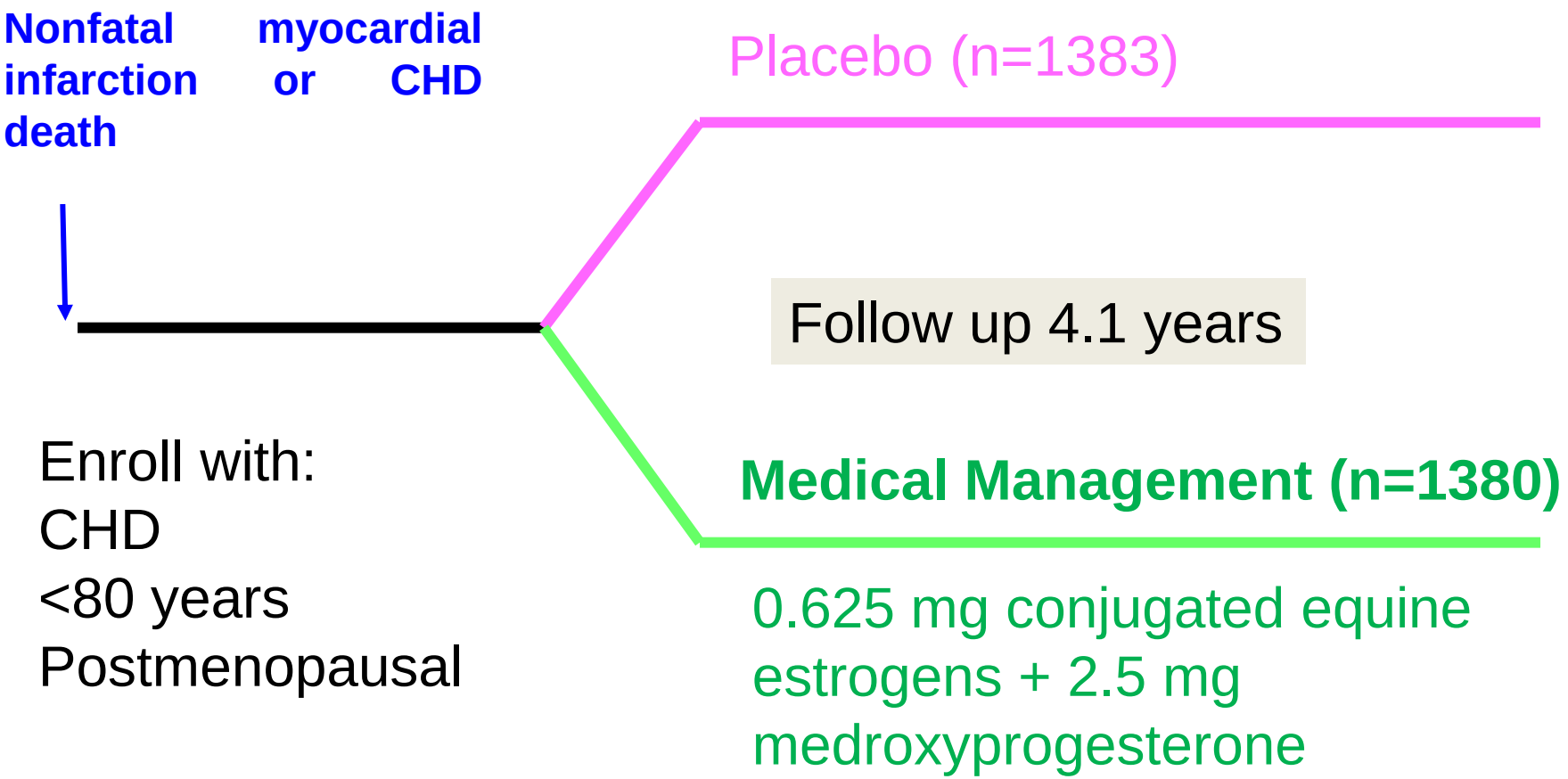
MANY OBSERVATIONAL studies have found lower rates of coronary heart disease (CHD) in women who take postmenopausal estrogen than in women not receiving this therapy.[1-5] This association has been reported to be especially strong for secondary prevention in women with CHD, with hormone users having 35% to 80% fewer recurrent events than nonusers.[6-12] If this association is causal, estrogen therapy could be an important method for preventing CHD in postmenopausal women. However, the observed association between estrogen therapy and reduced CHD risk might be attributable to selection bias if women who choose to take hormones are healthier and have a more favorable CHD profile than those who do not.[13-15] Observational studies cannot resolve this uncertainty.

The Heart and Estrogen/progestin Replacement Study (HERS)

The study question:

Does estrogen plus progestin therapy alter the risk for CHD events in postmenopausal women with established coronary disease?

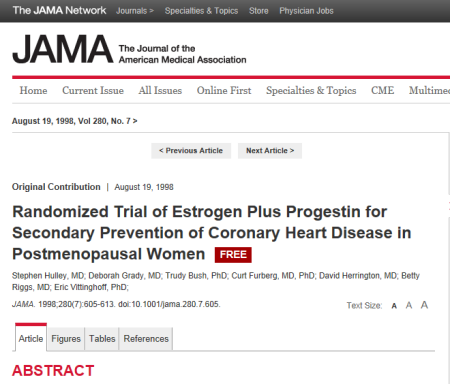
The Study Design



The Heart and Estrogen/progestin Replacement Study (HERS)

The major findings:

In postmenopausal women with established coronary disease and an average age of 66.7 years, daily use of conjugated equine estrogens and medroxyprogesterone acetate did not reduce the overall risk for MI and CHD death or any other cardiovascular outcome during an average of 4.1 years of follow-up. This therapy did increase the risk of venous thromboembolic events and gallbladder disease.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August 19, 1998, Vol 280, No. 7 >

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JAMA. 1998;280(7):605-613. doi:10.1001/jama.280.7.605.

Text Size: A A A

Article Figures Tables References

ABSTRACT

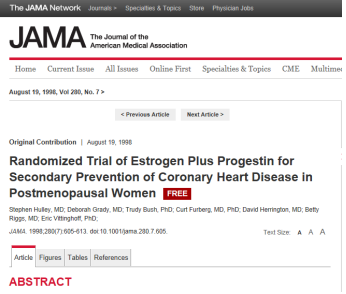
Background:

- Lipoprotein(a) [Lp(a)] has been found to be an independent risk factor for CHD events of men without known coronary artery disease.

- Few prospective studies have evaluated the importance of Lp(a) as a risk factor among women with CHD.

- Estrogen and the combination of estrogen and progestin lower Lp(a) levels in postmenopausal women.

- Because these studies have been conducted in women without CHD and without assessment of CHD outcomes, the clinical importance of lowering Lp(a) levels among women is unknown.



The study question:

What are the relationships among treatment with estrogen and progestin, serum Lp(a) levels, and subsequent CHD events in postmenopausal women?

The Study Design

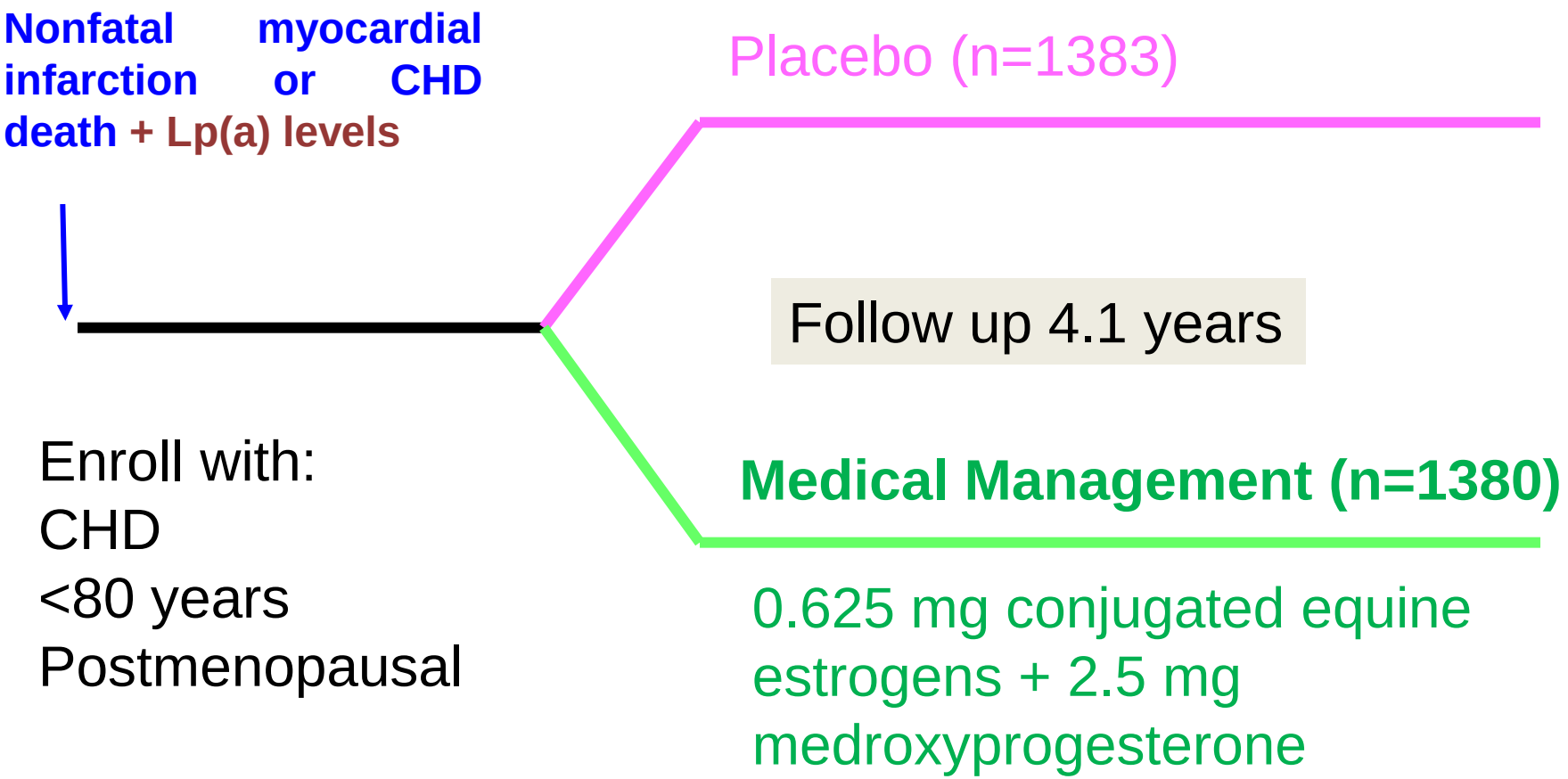


Table 2. Risk of Recurrent Coronary Heart Disease Events by Baseline Lipoprotein(a) Level Among Women Assigned to Placebo (n = 1383)*

	First Quartile (0.0-7.0 mg/dL) (n = 364)	Second Quartile (7.1-25.3 mg/dL) (n = 337)	Third Quartile (25.4-54.9 mg/dL) (n = 333)	Fourth Quartile (55.0-236.0 mg/dL) n = 348	*P* Value for Trend
Primary CHD events					
Events, No.	38	37	49	58	
Unadjusted HR (95% CI)	1.0	1.04 (0.7-1.6)	1.42 (0.9-2.2)	1.62 (1.1-2.4)	.008
Multivariate HR (95% CI)	1.0	1.01 (0.6-1.6)	1.31 (0.9-2.0)	1.54 (1.0-2.4)	.03
Myocardial infarction					
Event, No.	31	26	32	45	
Unadjusted HR (CI 95%)	1.0	0.90 (0.5-1.5)	1.14 (0.7-1.9)	1.55 (1.0-2.4)	.04
Multivariate HR (95% CI)	1.0	0.86 (0.5-1.5)	1.06 (0.6-1.8)	1.51 (0.9-2.5)	.08
CHD death					
Events, No.	10	12	21	16	
Unadjusted HR (95% CI)	1.0	1.27 (0.6-2.9)	2.31 (1.1-4.9)	1.64 (0.7-3.6)	.10
Multivariate HR (95% CI)	1.0	1.13 (0.5-2.7)	2.02 (0.9-4.4)	1.39 (0.6-3.2)	.25
CABG/PTCA					
Events, No.	64	56	57	82	
Unadjusted HR (95% CI)	1.0	0.93 (0.7-1.3)	0.99 (0.7-1.4)	1.41 (1.0-2.0)	.04
Multivariate HR (95% CI)	1.0	0.93 (0.7-1.3)	1.06 (0.7-1.5)	1.61 (1.1-2.3)	.006
Unstable angina					
Events, No.	29	31	25	35	
Unadjusted HR (95% CI)	1.0	1.16 (0.7-1.9)	0.96 (0.6-1.6)	1.28 (0.8-2.1)	.49
Multivariate HR (95% CI)	1.0	1.21 (0.7-2.0)	1.07 (0.6-1.8)	1.54 (0.9-2.6)	.17

*CHD indicates coronary heart disease; HR, hazard ratio; CI, confidence interval; CABG, coronary artery bypass graft surgery; and PTCA, percutaneous transluminal coronary angioplasty. Primary CHD events include nonfatal myocardial infarction and CHD death. Models are adjusted for other predictors ($P<.10$) including race/ethnicity, diabetes mellitus, waist-to-hip ratio, tobacco use, high- and low-density lipoprotein cholesterol levels, triglyceride level, and use of lipid-lowering agents, aspirin, and calcium channel blockers. To convert mg/dL to µmol/L, multiply by 0.0357. One subject was missing baseline lipoprotein(a) level and so was not included in the analysis.

The major findings:

Women in the highest Lp(a) quartile had a 54% (95% confidence interval [CI], 0%-140%) increased risk of primary CHD events compared with women in the lowest Lp(a) quartile.

Lp(a) is an independent risk factor for recurrent CHD in postmenopausal women and that treatment with estrogen and progestin lowers Lp(a) levels.

Estrogen and progestin therapy appears to have a more favorable effect (relative to placebo) in women with high initial Lp(a) levels than in women with low levels.

ORIGINAL CONTRIBUTION

Estrogen and Progestin, Lipoprotein(a), and the Risk of Recurrent Coronary Heart Disease Events After Menopause

Michael G. Shlipak, MD, MPH
Joel A. Simon, MD, MPH
Eric Vittinghoff, PhD
Feng Lin, MS
Elizabeth Barrett-Connor, MD
Robert H. Knopp, MD
Robert I. Levy, MD
Stephen B. Hulley, MD, MPH

Context Lipoprotein(a) [Lp(a)] has been identified as an independent risk factor for coronary heart disease (CHD) events. However, few data exist on the clinical importance of Lp(a) lowering for CHD prevention. Hormone therapy with estrogen has been found to lower Lp(a) levels in women.

Objective To determine the relationships among treatment with estrogen and progestin, serum Lp(a) levels, and subsequent CHD events in postmenopausal women.

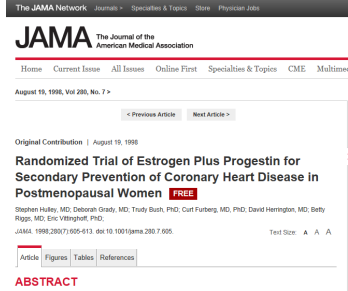
Design and Setting The Heart and Estrogen/progestin Replacement Study (HERS), a randomized, blinded, placebo-controlled secondary prevention trial conducted from January 1993 through July 1998 with a mean follow-up of 4.1 years at 20 centers.

Participants A total of 2763 postmenopausal women younger than 80 years with coronary artery disease and an intact uterus. Mean age was 66.7 years.

Intervention Participants were randomly assigned to receive either conjugated equine estrogens, 0.625 mg, plus medroxyprogesterone acetate, 2.5 mg, in 1 tablet daily (n = 1380), or identical placebo (n = 1383).

Main Outcome Measures Lipoprotein(a) levels and CHD events (nonfatal myocardial infarction and CHD death).

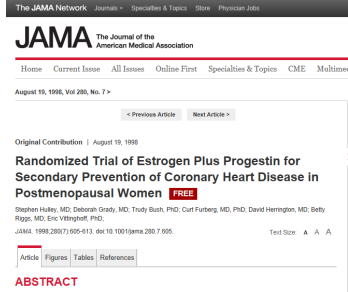
LIPOPROTEIN(A) [LP(A)] HAS BEEN found to be an independent risk factor for coronary heart disease (CHD) events in most[1-7] but not all[8-10] prospective studies of men without known coronary artery disease. Few pro-



Am J Med. 2012 August ; 125(8): 804–810. doi:10.1016/j.amjmed.2012.02.014.

Placebo adherence and mortality in the Hormone and Estrogen/ Progestin Replacement Study

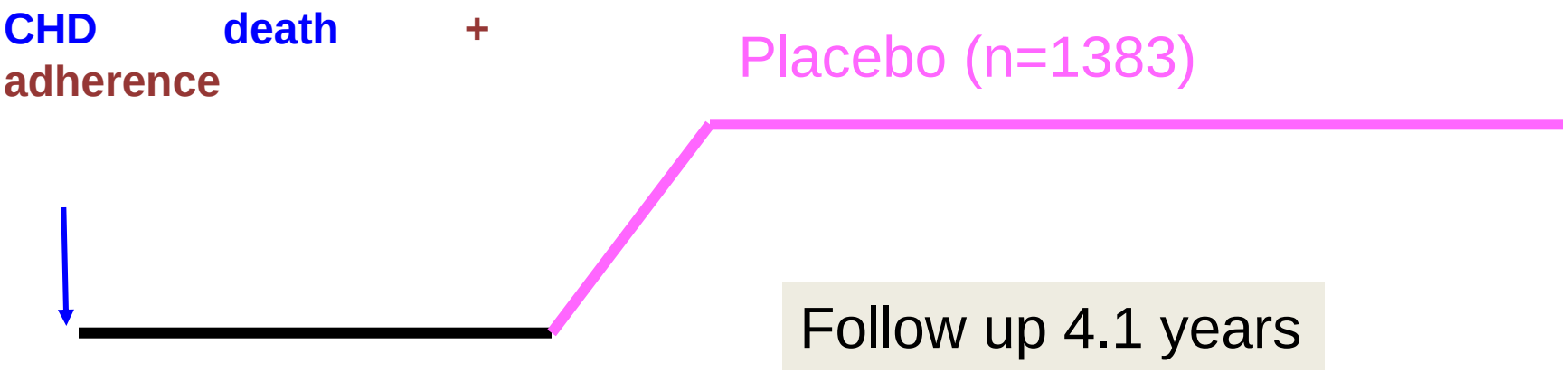
Amy M. Padula, Ph.D., M.Sc.[1,2], **Alice R. Pressman, Ph.D., M.S.**[3], **Eric Vittinghoff, Ph.D.**[4], **Deborah Grady, M.D., M.P.H.**[5], **John Neuhaus, Ph.D.**[4], **Lynn Ackerson, Ph.D.**[3], **Peter Rudd, M.D.**[2], and **Andrew L. Avins, M.D., M.P.H.**[3,4,5]



Background:

Double-blind clinical trials provide a unique opportunity to measure the health effects of adherence itself by studying only the placebo-allocated participants. In post-hoc analyses of several clinical trials, participants with higher adherence to placebo had substantially reduced mortality compared to those with lower adherence [1–7]. Possible explanations for this relationship include publication bias, adherence as a proxy for a healthy lifestyle, and time-dependent confounding (i.e., a serious underlying disease process causing reduced compliance as well as death). This report is part of a series of detailed analyses examining the association of placebo adherence with mortality [8,9].

The Study Design



Enroll with:
CHD
<80 years
Postmenopausal

Am J Med. 2012 August ; 125(8): 804–810. doi:10.1016/j.amjmed.2012.02.014.

Placebo adherence and mortality in the Hormone and Estrogen/ Progestin Replacement Study

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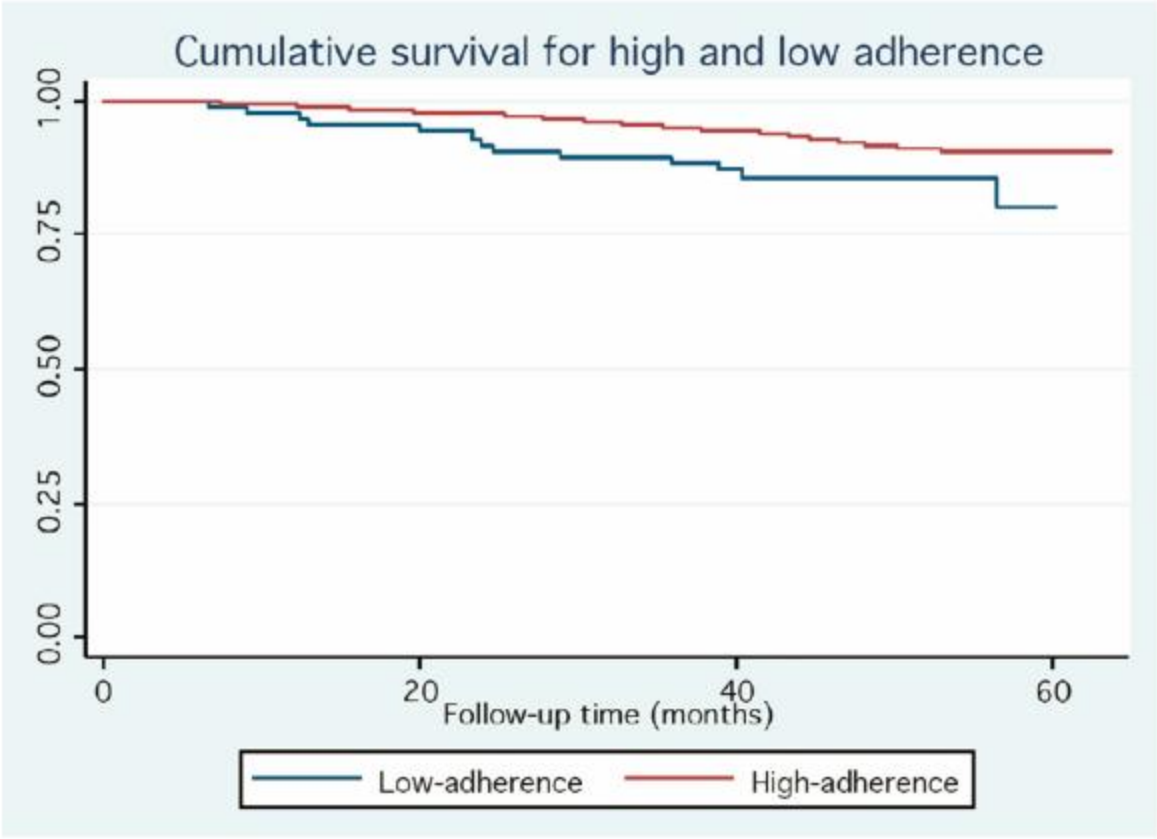


Figure 2.
Kaplan Meier curves of total mortality for higher-adherent (blue line) and lower-adherent (red line) placebo-allocated participants in the HERS study.

Secondary data utilization

- Senior colleagues
- Databases at home institutions
- Databases at other institutions
- Obtain permission and be specific about what information is sought

Secondary data utilization

- The choice of design depends on the goal of the trial.

- **Proper design is critical; analysis cannot rescue improper design.**

Secondary data utilization

- Research questions
  - What questions will the study address?
- Background and significance
  - Why are these questions important?
- Design
  - How is the study structured?

  Time frame

  Epidemiologic approach
- Subjects
  - Who are the subjects and how will they be selected?

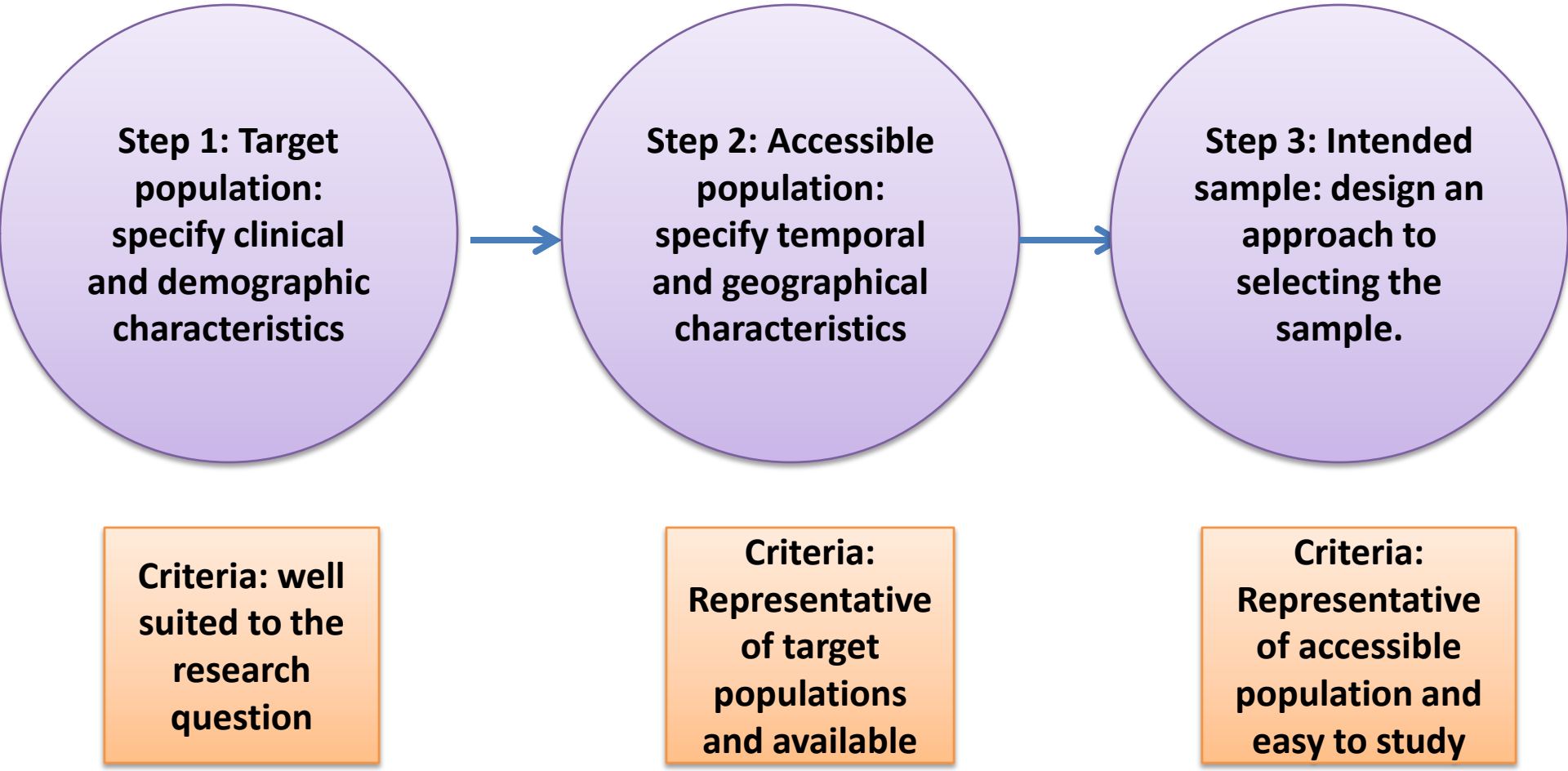
  selection criteria

  sampling design

Secondary data utilization

1. Mastering the literature
2. Be alert to new ideas and techniques (meeting/contacts)
3. Keeping the imagination roaming
4. Choosing an experienced mentor
5. Importance of getting good advice; most scientists respond favorably to requests for good advice.

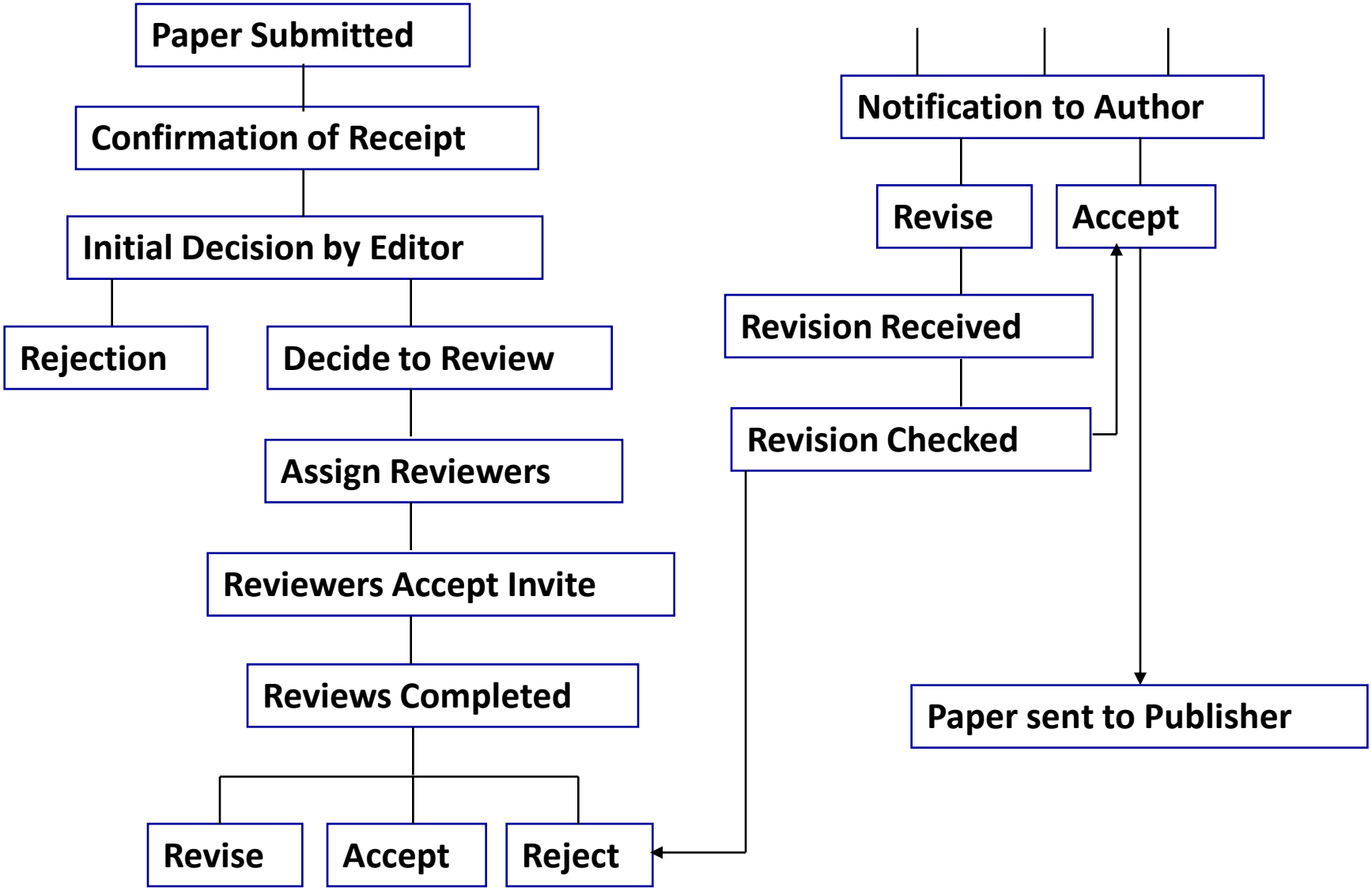
Secondary data utilization



Effective Writing for Biomedical Publications

- Secondary data utilization
- How to respond to reviewer critique

Peer Review Process



The Top 10 Reasons Why Manuscripts Are Not Published

10. Picking the wrong journal
9. Submitting a manuscript in a format that does not match what the journal publishes
8. Not following the manuscript preparation instructions
7. Poor writing
6. Getting carried away in the discussion
5. Suboptimal reporting of the results
4. Inadequate description of the methods
3. Poor study design
2. **Failure to revise and resubmit following peer review**
1.Failure to write and submit a full manuscript after presenting the abstract.

Respiratory Care (2004) 40:1246

How to respond to critiques

- The reviewer determines if your manuscript is suitable for publication in the journal to which it is submitted.

- Novelty
- Significance
- Relevance
- Quality and novelty of the experimental design
- Data interpretation
- Style and presentation of the data.

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- Novelty
- Significance
- Relevance
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- Style and presentation of the data.

How to respond to critiques

- Your letter to the editor should start politely.
- Response letters should state that the author thanks the reviewers for their time and effort and their contributions to the work.
- Address the comments of the reviewers and/or conduct the recommended experiments strengthened the work.
- The goal is to move the work forward and figure out how to satisfy the reviewer.

How to respond to critiques

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- Address the comments of the reviewers and/or conduct the recommended experiments strengthened the work.

- The goal is to move the work forward and figure out how to satisfy the reviewer.

How to respond to critiques

- Provide a point by point response to each reviewer's concerns.
- If your response is supported by the literature, quoting papers and supplying references will strengthen your point.
- In places where you and the reviewer agree, you should note in the manuscript where you have made revisions reflecting the reviewer's concerns. This will help the editor and the reviewer (if the manuscript is sent out for re-review) locate your changes and determine if you have really addressed the issues.

An Integrated Genomic Analysis of Human Glioblastoma Multiforme

D. Williams Parsons,[1,2*] Siân Jones,[1*] Xiaosong Zhang,[1*] Jimmy Cheng-Ho Lin,[1*] Rebecca J. Leary,[1*] Philipp Angenendt,[1*] Parminder Mankoo,[3] Hannah Carter,[3] I-Mei Siu,[4] Gary L. Gallia,[4] Alessandro Olivi,[4] Roger McLendon,[5] B. Ahmed Rasheed,[5] Stephen Keir,[5] Tatiana Nikolskaya,[6] Yuri Nikolsky,[7] Dana A. Busam,[8] Hanna Tekleab,[8] Luis A. Diaz Jr.,[1] James Hartigan,[9] Doug R. Smith,[9] Robert L. Strausberg,[8] Suely Kazue Nagahashi Marie,[10] Sueli Mieko Oba Shinjo,[10] Hai Yan,[5] Gregory J. Riggins,[4] Darell D. Bigner,[5] Rachel Karchin,[3] Nick Papadopoulos,[1] Giovanni Parmigiani,[1] Bert Vogelstein,[1]† Victor E. Velculescu,[1]† Kenneth W. Kinzler[1]†

Glioblastoma multiforme (GBM) is the most common and lethal type of brain cancer. To identify

mary and secondary GBMs. This issue is further confounded by the possibility that a fraction of GBMs designated as primary tumors may follow a sequence of genetic events similar to that of secondary lesions but not come to clinical attention until malignant progression to a GBM has occurred.

The comprehensive elucidation of genetic alterations in GBMs could provide novel targets that might be used for diagnostic, prognostic, or therapeutic purposes as well as to identify subgroups of patients that preferentially respond to particular targeted therapies. The determination of the human genome sequence and improvements in sequencing and bioinformatic technol-

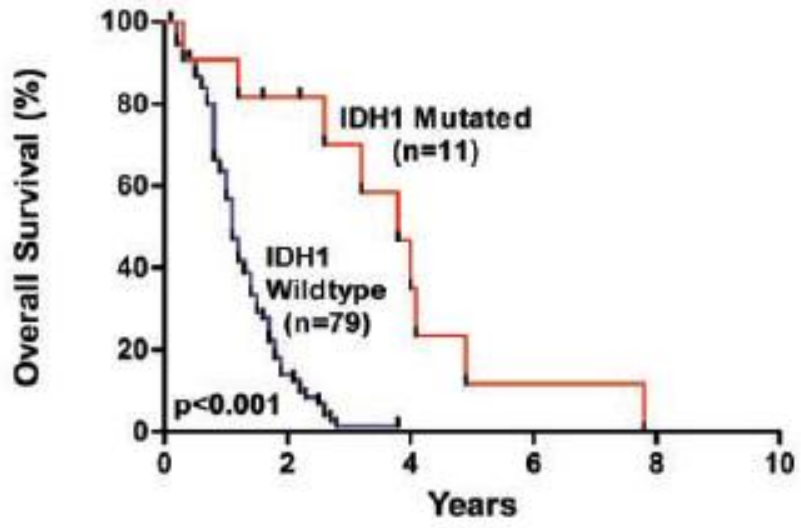

Fig. 2. Overall survival according to *IDH1* mutation status. The hazard ratio for death among

Science. 2008 Sep 26;321(5897):1807-12. Epub 2008 Sep 4.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

IDH1 and *IDH2* Mutations in Gliomas

Hai Yan, M.D., Ph.D., D. Williams Parsons, M.D., Ph.D., Genglin Jin, Ph.D., Roger McLendon, M.D., B. Ahmed Rasheed, Ph.D., Weishi Yuan, Ph.D., Ivan Kos, Ph.D., Ines Batinic-Haberle, Ph.D., Siân Jones, Ph.D., Gregory J. Riggins, M.D., Ph.D., Henry Friedman, M.D., Allan Friedman, M.D., David Reardon, M.D., James Herndon, Ph.D., Kenneth W. Kinzler, Ph.D., Victor E. Velculescu, M.D., Ph.D., Bert Vogelstein, M.D., and Darell D. Bigner, M.D., Ph.D.

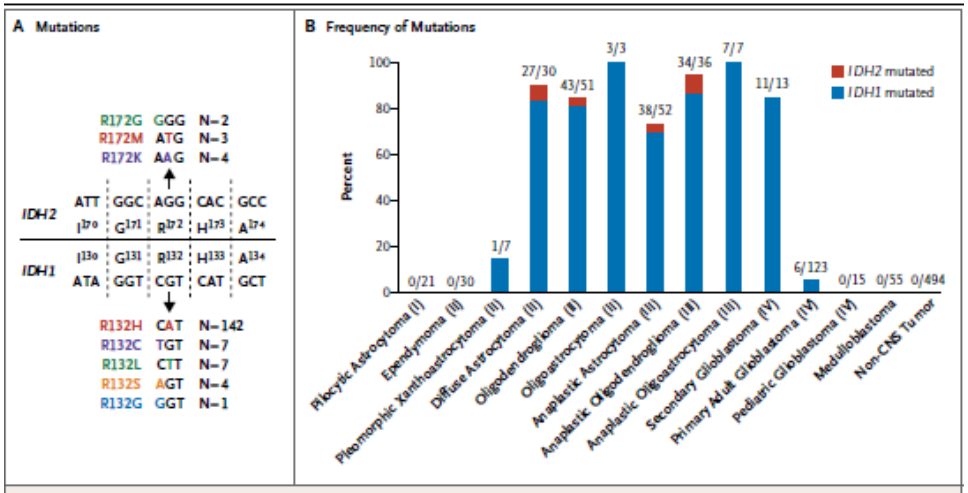

Figure 1. *IDH1* and *IDH2* Mutations in Human Gliomas.

Panel A shows mutations at codon R132 in *IDH1* and R172 in *IDH2* that were identified in human gliomas, along with the number of patients who carried each mutation. Codons 130 to 134 of *IDH1* and 170 to 174 of *IDH2* are shown. Panel B shows the number and frequency of *IDH1* and *IDH2* mutations in gliomas and other types of tumors. The roman numerals in parentheses are the tumor grades, according to histopathological and clinical criteria established by the World Health Organization. CNS denotes central nervous system.

How to respond to critiques

•

Dear Dr. Du

: Your manuscript entitled, "Treatment of Femoral Head Loss Secondary Septic Arthritis in Infancy With Modification of Albee's Arthroplasty," number JBJS-D-09-00201, has been reviewed by two experienced pediatric orthopaedic surgeons, as well as by myself. The comments of these clinical reviewers are included below. In addition, your manuscript was reviewed by one of the methodology and statistics editors for JBJS and the comments of that editor are also below.

Based on the reviews, the decision has been made to not accept your manuscript for publication in JBJS. I know this is not the decision you desired, but I hope that the comments of the three reviewers will be of help to you as you revise your manuscript for submission to another orthopaedic journal. Thank you for submitting your research report to JBJS for our consideration.

In accordance with our Copyright Transfer and Author Agreement, The Journal hereby re-conveys to the authors, without any representation, warranty or recourse, all of the rights (including copyrights) in the Work that were assigned to The Journal by the authors under that Agreement and are now held by The Journal.

Sincerely,

Vernon T. Tolo, MD
Deputy Editor

How to respond to critiques

- August 23, 2009
- Dear Dr. Vernon T. Tolo,
- Thank you for your having our manuscript (JBJS-D-09-00201) entitled “Treatment of Femoral Head Loss Secondary Septic Arthritis in Infancy with Modification of Albee's Arthroplasty” reviewed. We regret to learn the decision by JBJS not to accept our manuscript. However, we are very encouraged by the positive comments by the reviewers who have pointed out problems and deficiencies with the manuscript, but most of all they recognize the value of our work, the publication of which will be of great help to our fellow pediatric orthopedic surgeons in managing the severe sequelae of septic arthritis of the hip in young children.

- Start politely and thanks the editor for sending the manuscript for review.
- Be positive and emphasize the value/significance of your work.

How to respond to critiques

- We have revised the manuscript in accordance with the suggestions by the reviewers. In it, we have addressed almost all of the concerns by the reviewers and have incorporated answers to their questions in the revised manuscript. In addition, we have enlisted the help of Dr. Bo Cui at the Department of Surgery, Duke University Medical Center, Durham, NC, USA in the final revision of the manuscript. We have also sought the advice for statistical analysis from Dr. Xiutang Cao, a statistician at the Fourth Military Medical University China. We would like to ask your kind reconsideration of the manuscript either as a new manuscript or as a revised manuscript and we would also like to have the same reviewers review the manuscript if possible. Though septic arthritis of the hip in young children is uncommon, it is often devastating to those who have the disease. Our experience and the results of our retrospective study of modified Albee's arthroplasty in young patients with the severe sequelae of septic arthritis of the hip will be useful for pediatric orthopedic surgeons all over the world who face this problem rarely.

- Address comments/concerns by the reviewers.
- Be specific about your request.
- Emphasize the value of your work

How to respond to critiques

- Again all the authors have read the final manuscript and agreed to its publication if accepted by the journal. No duplicate publication or submission of the manuscript has been made elsewhere.
- We have detailed our responses to the reviewers and also documented the changes in the responses that are appended at the end of this letter.
- If you or the reviewers have any questions, please do not hesitate to contact me.
- Thank you for your consideration of our manuscript.

- Indicate that you have made appropriate changes in the manuscript.

A commentary by Paul D. Sponseller, MD, is available at www.jbjs.org/commentary and as supplemental material to the online version of this article.

Evaluation of the Modified Albee Arthroplasty for Femoral Head Loss Secondary to Septic Arthritis in Young Children

By Xue-dong Li, MD, PhD, Bin Chen, MD, Jun Fan, MD, PhD, Chuang-yi Zheng, MD, Dong-xin Liu, MD, PhD, Hu Wang, MD, PhD, Xue Xia, MD, Shi-jun Ji, MD, and Shi-xin Du, MD, PhD

Investigation performed at the 1st Affiliated Hospital, Medical College of Shantou University, Shantou, Guangdong, China

Background: Surgical treatment options for femoral head deficiency in infants secondary to septic arthritis of the hip are varied and associated with uncertain long-term outcomes. The modified Albee arthroplasty has been considered an acceptable procedure; however, the long-term outcomes of this procedure have not been reported, to our knowledge. We evaluated the long-term outcomes of the modified Albee arthroplasty in young patients with severe sequelae of septic arthritis of the hip.

Methods: We retrospectively studied twenty-one children (twenty-one hips) in whom Choi type-IVB sequelae of septic arthritis of the hip had been treated with a modified Albee arthroplasty and six patients with the same sequelae who had been managed with simple observation. The Trendelenburg sign, pain, the range of motion, hip function, the Harris hip score, and limb-length discrepancy were assessed clinically. Remodeling of the femoral head, hip stability, and arthritic changes in the hip were evaluated radiographically.

Commentary & Perspective on "Evaluation of the Modified Albee Arthroplasty Femoral Head Loss Secondary to Septic Arthri Young Children" by Xue-dong Li, MD, PhD, et al.

By Paul D. Sponseller, MD,*
Johns Hopkins Medical Institutions, Baltimore Maryland

THE JOURNAL OF BONE & JOINT SURGERY
JB&JS
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In this month's issue of JBJS, Li et al. report the largest series of post-sepsis Choi type-IVB hip deformities that have been treated with this method. This series should be considered in the context of other reports on the same procedure. Why report on this "old" procedure now? The answer is because the solution seems still valid and this series is the largest one (twenty-one hips) and has the longest follow-up (minimum, three years; mean, ten years) with the most information on outcomes. The sample size and the follow-up are significant. Finally, this report can provide useful guidance to pediatric orthopaedic surgeons all over the world who treat this condition.

Commentary & Perspective By Paul D. Sponseller, MD*, Johns Hopkins Medical Institutions, Baltimore Maryland on:

"Evaluation of the Modified Albee Arthroplasty for Femoral Head Loss Secondary to Septic Arthritis in Young Children" by Xue-dong Li, MD, PhD, et al.

The article is also useful in part because it contains a detailed description of the procedure. This instruction, in combination with the decade-long follow-up of this uncommon problem, provides valuable information to guide us. The series of three line drawings illustrating the procedure is practical and ***helps make this a landmark paper.***

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Evaluation of the Modified Albee Arthroplasty for Femoral Head Loss Secondary to Septic Arthritis in Young Children

Surgical Technique

By Xue-dong Li, MD, PhD, Bin Chen, MD, Shao-wei Luo, MD, Shi-jun Ji, MD, and Shi-xin Du, MD, PhD

Investigation performed at the 1st Affiliated Hospital, Medical College of Shantou University, Shantou, Guangdong, China

The original scientific article in which the surgical technique was presented was published in JBJS Vol. 92-A, pp. 1370-80, June 2010

ABSTRACT FROM THE ORIGINAL ARTICLE

BACKGROUND: Surgical treatment options for femoral head deficiency in infants secondary to septic arthritis of the hip are varied and associated with uncertain long-term outcomes. The modified Albee arthroplasty has been considered an acceptable procedure; however, the long-term outcomes of this procedure have not been reported, to our knowledge. We evaluated the long-term outcomes of the modified Albee arthroplasty in young patients with severe sequelae of septic arthritis of the hip.


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