ICM 2018
Mission

- Bring together expert doctors and scientists from around the world to determine the state of art related to orthopedic infections
ICM 2018
Mission

- Improve musculoskeletal care of patients by preventing or better treating orthopedic infections
Background

• April 2012!!!!


Consensus statement from the consensus conference on bilateral total knee arthroplasty group.

Memtsoudis SG1, Hargett M, Russell LA, Parvizi J, Cats-Baril WL, Stundner O, Sculco TP; Consensus Conference on Bilateral Total Knee Arthroplasty Group.

Collaborators (31)

Author information
Background

• July 2012!!!!
First International Consensus on Periprosthetic Joint Infection
August 1-3, 2013
Javad Parvizi MD, FRCS
Thomas Jefferson University, Philadelphia
ICM 2013 Statistics

- Delegates Invited
- Delegates Attended
- Countries
- Societies

Comparison between 2013 and 2018.
Javad Parvizi
Hi Willem! hope all is well with you and your surgery. We are thinking about you. I have this document as the latest one. Can we please find a time to schedule a call to discuss?

Willem-Jan Metsemakers
to Charalampos, me, ailie

Dear Javad,

Thank you, still in the hospital but feeling better.
I emailed you the updated version earlier. I included it in this email again.
The version you emailed is not up to date for my feeling and I don’t think this is sufficient to go online with.
I cc Lampis maybe he can have a quick look?

Best regards,

Willem
Step I
Selection of Delegates
August 2016 - December 2016
Step I: Selection of Delegates

- Publication records (five papers in five years)
- Society nomination
- Clinical care
- Basic science research
Step I: Selection of Delegates

- Apologies to those who deserve to be here and could not
  - Declined (23 people)
  - Communication
  - Failure in mechanism
Step II
Collection of Questions
December 2016 – April 2017

1. After a patient undergoes MRSA decolorization, is there a need to re-screen the patient?
4. Are there any genetic factors that predispose patients to SSI/PJI or predict the success of the treatment for SSI/PJI?
5. a) Do underweight patients (low BMI) have a higher risk of SSI/PJI following orthopedic procedures? b) If yes, does increasing the body mass index in underweight patients reduce the risk of SSI/PJI?
14. Do antplatelet drugs need to be withheld pre-operatively to reduce the risk for subsequent SSI/PJI?
15. Do patients need to refrain from getting the surgical incision wet or submerged in water to prevent SSI/PJI? If so, for how long postoperatively?
16. Does a patient with a colostomy have an increased risk for SSI/PJI?
17a. Does a prior arthroscopy of the hip joint increase the risk of a subsequent SSI/PJI in patients undergoing elective total hip arthroplasty?
17b. Does a prior arthroscopy of the knee increase the risk of a subsequent SSI/PJI in patients undergoing elective arthroplasty?
18. Does a prior surgical procedure (with or without retained hardware) in the same joint as the arthroplasty increase the risk of subsequent SSI/PJI? If so, what can be done to reduce the risk of SSI/PJI?
19. Does a prolonged hospitalization prior to elective total joint arthroplasty increase the risk of subsequent SSI/PJI?
22. Does allogeneic blood transfusion increase the risk of SSI/PJI?
25. Does bariatric surgery reduce the risk of SSI/PJI in patients with obesity?
Step II: Collection of Questions

- Each delegate asked to send 5-10 questions
- 3,210 questions received
Step III

Ranking of Questions
April 2017- August 2017
Step III: Ranking of Questions

- Questions were ranked by the delegates in the order of priority
- Duplicates were removed
- Down to 650 questions
Step IV
Evaluation of Questions
August 2017-November 2017
Step IV: Evaluation of Questions

- Rewrite according to Delphi
- Suggestive stems
  - (“what evidence is there to prove…”)
- Committal
  - (“what is the role of..”)
- Preliminary literature search
Step V
Assignment of Questions
November 2017 - December 2017
Step V: Assignment of Questions

- Based on publication records
- Delegate desire
- Proposed question
- Each question was assigned to at least two delegates (opposing views)
Step VI
Systematic Review
December 2017 - March 2018
Step VI: Systematic Review

- Over 200,000 publications reviewed
Step VI: Systematic Review

- Over 2/3 delegates did their work
- Multiple email reminders
- Those not answered were reassigned (internal)
Step VII
Interdelegate Discussions
March 2018 - April 2018
Step VII: Inter-delegate Discussions

- Documents received reviewed
- Forwarded to other delegates
- Ongoing discussions (>4000 emails)
Jorge Manrique <jorgemanrique@md@gmail.com>

to me, allie  

Dr. Panizi,

Please find attached T46.
I have a few more that I am in the process of receiving and will send them to you shortly.

Thank you,

Jorge
Step VIII: Document Merging

- Documents merged (editors)
- Reviewed again
- Sent to corresponding delegates
Step IX
Document Evaluation by Delegates
May 2018 - June 15, 2018

HK-1 - POC DX TESTS

**Response/Recommendation:** Yes, there are several point of care tests which can be added to the diagnostic modalities of PJI. Good quality data support the usefulness and reliability of quick tests like Leukocyte Esterase (LE) strip test and Alpha Defensins lateral flow test (Spectrum). PJI quick test. Diagnostic criteria for PJI should be updated and include these tests.

**Strength of the Recommendation:** Strong

**Rationale:**
A point-of-care test (POCT) is defined as medical diagnostic, and is used at or near the point of care, at the time and place of patient care. These are rapid and simple medical tests that can be performed at the bedside. The idea behind POCT is to bring the test conveniently and immediately to the patient.
Step IX: Document Evaluation by Delegates

- Documents were posted live on the website
- App generated
- Delegates gave feedback
Step X

Final Evaluation by Delegates

July 1-25, 2018
Step X: Final Review

- Additional Review (JP/Editorial Team)
- Additional Input from experts
- Last check of published literature
Step XI
Face to Face Meeting - Pre Vote Discussions
July 25-26, 2018
Step XI: Pre-Vote Discussion

- Face to face meeting
- "Controversial questions/recommendations discussed"
Step XII
Voting
July 26-27, 2018
Step XII: Voting

- Face to face meeting
- Voting
- Live ARS system
HK-29 (former HK-22) Does changing the drapes during debridement, antibiotics, and implant retention affect the rate of success?

RESEARCHED BY:

Plamen Kinov MD, Bulgaria

Akos Zahar MD, Germany

Thorsten Gehrke MD, Germany
Literature:

• There are no studies that assess the impact of changing the drapes during DAIR.

• After a literature review of 51 papers, only one study was identified that indirectly mentioned the use of clean draping during the surgical procedure.

• Changing the drapes during DAIR can be performed at the surgeon’s discretion.
**Recommendation:** The impact and effectiveness of changing the drapes during debridement, antibiotics, and implant retention (DAIR) has not been investigated and therefore it can be performed at the surgeon’s discretion.

**Level of Evidence:** Consensus

A. Agree
B. Disagree
C. Abstain
Step XIII
Dissemination of the Information
Step XIII
Dissemination of the Information

- J. of Shoulder and Elbow Surg
- Foot and Ankle Int.
- Spine
- Trauma
- Sports
Step XIII
Dissemination of the Information
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Translations

- Spanish
- Chinese
- Japanese
- Italian
- Korean
- Portuguese
- Russian
- Turkish
- Farsi
- Czech
- Indonesian
- German
- Polish
- Arabic
- Ukrainian
- French
- Greek
- Bulgarian
- Romanian
- Dutch/Africaans
Why bother?
Literature is not definitive on many issues
Much of what we have is based on thin science, if any at all.
Challenges of Generating Evidence

- To do studies on infection, large sample sizes are needed.
  - n=5,000, n= 22,000, n= 36,000
Challenges of Generating Evidence

- Not everything we do needs “randomized, prospective studies”
Scholar Innovators

Glove during surgery

Hand washing - sterile techniques

Antibiotics
Abstract The ethics of clinical research requires equipoise, a state of genuine uncertainty on the part of the clinical investigator regarding the relative merits of the treatments A and B. The investigator discovers that one treatment is of superior therapeutic value, but the difference is not statistically significant. The current understanding of this requirement, which entails that the investigator must remain equipoise throughout the course of the trial, presents some obvious problems.

THERE is widespread agreement that ethics requires that each clinical trial have an integrative hypothesis in which some treatment B is superior to the baseline treatment A. It is necessary that the clinical investigator be in a state of genuine uncertainty regarding the relative merits of treatments A and B. If a physician knows that these treatments are not equivalent, ethics requires that the superior treatment be recommended.

Following Fried, I call this state of uncertainty about the relative merits of A and B “equipoise.”

Equipoise is an ethically necessary condition in all cases of clinical research. In trials with several arms, equipoise must exist between all arms of the trial; otherwise the trial design should be modified to exclude the inferior treatments. If equipoise is disturbed during the course of a trial, the trial may need to be terminated and all subjects previously enrolled, as well as other patients within the relevant population, may have to be offered the superior treatment.

It has been rigorously argued that a trial with a placebo is ethical only in investigating the treatment, in which there is no known treatment. This argument reflects a special application of equipoise to the ethical evaluation of placebo-controlled trials. Although equipoise has commonly been defined in an abstract way, in the investigator's hands it means “an equipoise of all controlled clinical trials, whether or not they are randomized, placebo-controlled, or not, if equipoise is most readily satisfied by the requirement that equipoise can be stated as a result of the failure to enroll enough patients. An alternative concept of equipoise, which would allow for the termination of a trial, is the “clinical equipoise” that is, the equipoise that exists as does any other equipoise.

As a result of the failure to enroll enough patients, equipoise may be lost. This is evidenced by the failure to resolve these problems by a way that would permit clinical equipoise to prevail. This paper argues that these problems are predicated on a faulty concept of equipoise. A correct understanding of equipoise as an ethical requirement of clinical trials is proposed, and its implications are explored.

Many of the problems raised by the requirement for equipoise are familiar. Shaw and Chatiner have written that a clinical investigator who “knows, or has good reason to believe, that one arm of the trial is superior may not be ethically participate.” But the reasoning or preliminary results that prompt the trial (and that may themselves be ethically mandatory) may jolt the investigator (if not his or her colleagues) out of equipoise before the trial begins. Even if the investigator has decided in advance that A or B is better in terms of gross measures such as mortality and morbidity, equipoise may be disturbed because evidence differences in the quality of life (as in the case of two surgical approaches to the balance). In either case, in saying “we do not know” whether A or B is better, the investigator may feel jilted by the investigator's own equipoise before the trial begins. Even if the investigator has decided in advance that A or B is better in terms of gross measures such as mortality and morbidity, equipoise may be disturbed because evidence differences in the quality of life (as in the case of two surgical approaches to the balance). In either case, in saying “we do not know” whether A or B is better, the investigator may feel jilted by the investigator's own equipoise before the trial begins. Even if the investigator has decided in advance that A or B is better in terms of gross measures such as mortality and morbidity, equipoise may be disturbed because evidence differences in the quality of life (as in the case of two surgical approaches to the balance). In either case, in saying “we do not know” whether A or B is better, the investigator may feel jilted by the investigator's own equipoise before the trial begins. Even if the investigator has decided in advance that A or B is better in terms of gross measures such as mortality and morbidity, equipoise may be disturbed because evidence differences in the quality of life (as in the case of two surgical approaches to the balance). In either case, in saying “we do not know” whether A or B is better, the investigator may feel jilted by the investigator's own equipoise before the trial begins.
ICM Philadelphia

Thank You

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