FACE study (Fever and Antipyretic in Critical ill Evaluation study)

Fever was common in critically ill patients,

occurred in 20–70% of patients requiring intensive care

ICM 1999;25:668-73 Chest 2000:118:767-774 The AJMS 2006;332:61-67

Antipyretic was frequently prescribed. The cost for it was \$10,000 and \$29,000 per one ICU with 18 beds.

Arch Intern Med 2001,161:66-70

The study to assess the relationship between fever and mortality in non-neurological ICU. 24 papers

The study to assess the relationship between fever and mortality with antipyretic information.0 paper

The randomized controlled trial to assess the impact of antipyretic on the mortality 2 papers

Surgical ICU

RCT;Cooling

Aggressive vs permissive (cooling, if $38.5^{\circ}C$) vs (no cooling) Mortality 2/18(11%) vs 3/20(15%)(P=0.99)

Arch Intern Med 2001;161:121-123

Traumatic ICU

RCT;Cooling+Acetaminophen

Aggressive vs permissive (if 38.5°C>) vs (if 40.0°C>)

Mortality

7/44(16%) vs 1/38(2.6%)(P=0.06)

Surg infect(Larchmt) 2005;6:369-75

➤There are number of studies to assess the relationship between fever and mortality in non-neurological ICU.

However, all of them did not have any information of antipyretic.

➤There are two small, single center RCT, which suggested the potential risk of antipyretic.

Large RCT might be ethically difficult.

(Fever and Antipyretic in Critical ill Evaluation study)

Study aim

To know

➤How often fever is occurred in ICUs?

>Whether fever is associated with mortality?

>How often the antipyretic therapy is prescribed?

>Whether antipyretic is associated with mortality?

(Fever and Antipyretic in Critical ill Evaluation study)

Study populations

Adult non-neurological critically ill patients

(20 years old or older)

Requiring intensive care

more than 48 hours

Study period : 3 months + Follow up: 28 days

Patients demographics

Age-sex-weight-reason for admission-APACHE II Body temperature

Body temperature(every four hour) - Devices

<u>Antipyretic</u>

Type-dose-day and time

Steroids/extracoporial circuit

Dose-day and time

Infection

Culture proven or suspicion

Patients outcome

28days mortality • LOS in ICU•Kidney injury



Temperature indices
►Max temperature (+0.5°C band analysis)

➢Min temperature (+0.5°C band analysis)

➢Body temperature when first antipyretic is prescribed (+0.5℃ band analysis)

➢ Duration >38.0, 38.5, 39.0, 39.5 and 40.0°C



Antipyretic indices

>Whether antipyretic is used during ICU stay.

➤The antipyretic strategy (dose, type etc) prescribe from first BT>38.0°C to BT<38.0°C</p>

➤The antipyretic strategy (dose, type etc) prescribe from Max BT to BT<38.0°C.</p>

> (BT;Body temperature)



Pilot study

BT>38.0°C: about 50% of critically ill
 Antipyretic; prescribed for half of ICU patients
 ICU mortality; about 10%



Power calculation using pilot study

Assuming 7% increase in ICU mortality with antipyretic, a power of 0.80, and an α level of 0.05, we require 1200 participants.

Assuming 6% increase in ICU mortality with fever(BT>38.0°C), a power of 0.90, and an α level of 0.05, we require 1200 participants.

IRB

- •Feb 2009 Study have been approved.
- -IRB is required in each participated site.

Research meeting

Jan, April and Sep in each year Collaboration research meeting
Apr 2009; collaboration annual meeting (Fever in ICU)

FACE study bring us •••

 Pilot data for future study on Antipyretic Strategy.
 Infection cohorts.

2. The process to get grant for research

3. Collaboration research frame in Japan and Korea

Research conference conducting 3/year

Collaboration research in Japan and Korea

It is happening.

FACE will start Sep 2009, and finish the end of 2009.