Displaced femoral neck fractures: towards better practice
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Appendix 1

Physiologic Status Score (P.S.S.) study protocol

A prospective multicenter study to evaluate therapy using a Physiologic Status Score in patients with a displaced fracture of the femoral neck

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Final version, 20 May 2000
Study background

The femoral neck fracture  Half of the fractures of the hip are located in the proximal femoral neck. These intracapsular fractures are usually caused by a fall from standing position. They bear the most significant clinical implications. First, the fracture line runs almost parallel to the direction of all combined forces of muscle contraction and gravity. Secondly, at the intraarticular site of the fracture there is no cambium layer within the bone cortex, which is indispensable for periostal callus formation. Moreover, there is a high risk of damage to the arterial supply to the femoral head, which runs very near the surface of the femoral neck and head. After fracture, perfusion of the head may be compromised and explains the avascular necrosis after reduction and internal fixation.

Internal fixation versus hemiarthroplasty  In Lu-Yao's elaborate metanalysis of appropriate studies published between 1975 and 1990 only five comparative reports were included. They concluded that the risk of reoperation within two years after the initial treatment was 2.5 times higher in patients with internal fixation than those with a hemiarthroplasty. Concerning mobility, the metanalysis showed a benefit for hemiarthroplasty over internal fixation, but this was not significant. The deficiencies in the design of most studies weakens these conclusions. Of great concern is the selection bias toward internal fixation in patients who have a poorer overall prognosis. In addition few authors are specific in their indication for age.

At the end of the nineties, there is little discussion about the indication for primary internal fixation for undisplaced and displaced fractures of the femoral neck in young adults. In patients older than the age of 85, (hemi)arthroplasty is the widely accepted treatment due to the high incidence of failure after internal fixation. The issue of the most optimal and efficient treatment in the group of patients between the ages of 60 and 90, however, remains controversial.
Study design

Motivation  What can we do to improve the outcome of  femoral neck fractures? Many of the crucial factors are completely independant of the repair of the fracture and instead depend on general prefracture conditions. Studies in the past have randomly compared results of internal fixation and arthroplasty, but have failed to generate agreement of which method to choose for individual cases. Mostly only age is used as a prefracture criterium, and there is no general consensus of treatment between 60 and 90 years of age. Robinson et al developed a scoring system to quantify the true physiologic status of an individual patient between 65 and 85 years of age. Their prospective study centered on five main issues in the prefracture condition: mobility, accomodation, osteoporosis, cognition and medical condition. Statistical evaluation revealed significant differences between the two groups of patients in each of the five components, and each of the parameters would therefore appear to be valid. They concluded that the developed Physiologic Status Score (PSS) was a useful guide determining the appropriate treatment. In 42% of patients between 65 and 85 years of age with a high PSS (active and ambulatory patients), internal fixation was well justified at 21 months follow-up. There was a low incidence in fracture related complications, with 5% of the total group needing reoperation for infection, internal fixation failure and prosthetic dislocation. In the PSS, osteoporosis is measured by the Singh index. Koot et al studied the reliability of the Singh index compared with dual-energy X-ray absorptiometry. A very large interobserver variation was found.

The general opinion in surgical practice today is that patients are best off with a healed femoral neck fracture, their own femoral head and no avascular necrosis. We consider the PSS to be a promising strategic refinement of the prefracture condition leading to better results in internal fixation and hemiarthroplasty, with less revisions and so less cost to medical, social and rehabilitation resources.

The proportion of the Dutch population of 60 years and over is rapidly increasing and the number of 17,000 hip fractures a year (50% of which are fractures of the femoral neck) is expected to at least double by 2030. The impact on resources needed will be huge. In our opinion the strategies of osteosynthesis and endoprosthesis can be refined, our primary goals being less revisions, better functional outcome and less use of expensive resources.
Objective  The objective of this study is to assess the validity of the Physiologic Status Score as a strategic preoperative factor in making a choice between internal fixation and hemiarthroplasty. We hope to reduce the number of revisional procedures in patients with a fracture of the femoral neck.

Hypothesis  In a group of patients between 60 and 90 years old with a fracture of the femoral neck, patients assessed using the Physiologic Status Score and then treated with internal fixation or hemiarthroplasty will have less need for revisional procedures and therefore better functional outcome in the first two postoperative years.

Design  Prospective, multi-center trial

Summary  Consecutive patients between 60 and 90 years old presenting to the emergency department with a displaced (Garden III/IV) fracture of the femoral neck can be included.

The Physiologic Status Score (PSS) is used as a decisive criterium for internal fixation or hemiarthroplasty.

The osteoporosis component of the PSS as described by Robinson (using the Singh index) has been modified. Osteoporosis measurement will be done preoperatively by dual-energy X-ray absorptiometry (DXA scan).

Operations are performed by general surgeons, orthopaedic surgeons and resident surgeons under supervision with experience in both treatment modalities. Patients are included in one year and followed for a minimum of two years. Measurements are done by dual-energy X-ray absorptiometry (Dexa scan), plain X-ray evaluation, physical examination and current status evaluation on case report forms. The suggested follow-up intervals are 8 weeks, 1 year and 2 years postoperatively.

Duration  The inclusion of patients for the trial is planned to start from June 1st, 2000. Collection the sample size will take approximately one year. Follow-up of the last patients will therefore take place in May 2003. Final results are expected by December 2003.

Requirements  At the moment we estimate to need the cooperation of 10 participating centers (both university and district) with staff and residents experienced with both procedures. If each center includes 25 patients, the sample size can be collected in one inclusion year.
In addition, participating centers need to have a facility to perform the preoperative dual-energy X-ray absorptiometry scans.

**DXA scanning in the P.S.S. treatment group** The results of dexa scanning are given as a standard deviation compared with normal bone density. This standard deviation is either normal or abnormal for age. The non-fractured collum femoris is measured for the density of cortical bone and the lumbar vertebrae 1 to 4 (representative vertebrae, no fractured or impressed vertebrae) are measured for trabecular bone density. The position of the non-fractured leg in endorotation is standard. The actual scan takes about ten minutes. Extra radiation for the patient is minimal: 2,0 microSievert (WHO classification group I).

**Selection criteria** All patients presenting with a displaced fracture of the femoral neck are eligible for inclusion in this trial.

*Inclusion criteria:*
- Aged between 60 and 90 years old
- Displaced femoral neck fracture (Garden III and IV), no trochanteric fractures

*Exclusion criteria:*
- Undisplaced femoral neck fractures
  - Impacted, Pauwels I, Garden I type fractures
- Fractures of the femoral neck older than 1 week
  - Patients should be operated preferably within 48 hours, but fractures up to 1 week old can be included.
- Arthrosis
  - Patients with advanced arthrosis of the hip joint (aside from the fracture), who would normally be treated by total hip replacement.
  - Diagnostic signs on plain X-ray: subchondral sclerosis, narrowing of the articular cleft, formation of osteofytes and subchondral cyst formation.
- Rheumatoid arthritis
  - Patients with established rheumathoid arthritis or showing signs of this disease on plain X-ray are recommended to receive total hip replacement.
- Pathological fracture
  - Patients with a spontaneous fracture after a comparatively minor trauma who show
signs of osteolysis at the fracture sight on plain X-ray are not eligible.
- **Preoperative immobility**
  Patients who were already bed-ridden or bed-chair commuters before the fracture are not eligible.
- **Invalidity due to neurologic disease**
  Patients with M. Parkinson or CVA, who are immobile.

**Inclusion monitoring** Inclusion of eligible patients must be reported to the investigators by telephone. A special telephone number will be available for this purpose 24 hours a day. The treating physician provides the following information: patient initials, gender, date of birth and the side of the fractured hip. Furthermore, inclusion and exclusion criteria will be checked and questions regarding inclusion can be answered. The treating physician is then provided with a case report number.

**Treatment specifics**
General requirements.
- Consent Committee on Ethics of the Academic Medical Center

**Pre-operative requirements**
- Antibiotic prophylaxis may be administered according to hospital policy. The regimen should be recorded upon completion of recruitment of the participating centers.
  Recommendation: 2 grams Rocephin i.v., 30 minutes before incision.
- Anticoagulation treatment details are again left to hospital policy or treating physicians own preference as long as they are recorded before the trial starts.
  Recommendation: Fraxiparine 7500 IU s.c. daily.
- Traction of the fractured leg is not necessary.

**Operation** Before internal fixation, adequate reduction of displaced fractures of the femoral neck must take place. Inadequate reduction is a major risk factor in avascular necrosis and unstable fixation.
The CCD angle on the intraoperative image intensified pictures should be between 130 and 150 degrees in the AP view. In the lateral view optimal reduction is achieved when the anteversion angle is between 0 and 10 degrees, in which 0 degrees represents the long axis of the femoral shaft. Retroversion up to 20 degrees is acceptable.
In terms of the Garden Index the angle in the AP view should be between 160 and 180 degrees and in the lateral view between 165 and 190 degrees. Surgical approach and technique should be standard. Cementing of an endoprosthesis stem is mandatory.

**Implants**
- For internal fixation: Displaced Pauwels I or II type fracture:
  - preferably cannulated cancellous bone screws or Dynamic Hip Screw

- Displaced Pauwels III type fracture:
  - preferably Dynamic Hip Screw

- For hemiarthroplasty: All current cemented prostheses

**Post-operative**
- Regarding amount of pain and with the aid of physiotherapy, full weight bearing mobilization on the first postoperative day is started.

**Follow-up**
Data collection.
Applicable case report forms should be completed on admission, at operation, after the operation and upon discharge.
Patient follow-up is scheduled at 8 weeks, 1 and 2 years after the operation. At each of these times the Harris Hip Score is determined and documented on the case report form. An X-ray exam of the pelvis and axial hip is performed at 1 and 2 years. Additional case report forms are filled out at each follow-up period.

**Definition of end points**
Primary end points:
Revision of either primary internal fixation or hemiarthroplasty will be the main criterion of evaluation. Dislocation of an endoprosthesis with closed reduction is not considered as a revisional procedure.
Secondary end points:

1. Mortality
2. The change in Harris Hip Score (HHS) in the course of follow-up.
   
   The HHS is based on an assessment of four parameters: pain, function, range of motion and absence of deformity. Pain and function can be appreciated with 91 points and the remaining two qualities can increase the score to a maximum total of 100 points.
3. Complications, such as persistent pain, deep infection, any dislocation or deep venous thrombosis are also important parameters.

**Anticipated number of patients** Results of a meta-analysis results in 1994 showed a revision rate of 35% for IF and 16% for HA at 2 year follow-up. One-year mortality was 28% in both groups. If application of the PSS could achieve a revision rate reduction of 10% (35% to 25%) for IF at 2 year follow-up, one-sided 95% CI analysis with an alpha of 0.05 showed that 70 IF patients [upper limit 95% CI: 0.34] were required for inclusion. Expecting 40% of the total sample to be IF patients, 105 HA patients [upper limit 95% CI: 0.10] were required. The expected amount of HA patients was therefore enough to prove a significant reduction in revision from 16% to 6%. Anticipating a 2 year mortality rate of 30%, at least 70 + 105 + 85 = 250 patients were required.

**Ethics**

Declaration of Helsinki.

This study will be conducted in full accordance with the principles of the Declaration of Helsinki (as amended in Tokyo and Venice) and with the laws and regulations of the Netherlands.

Institutional Review Board (IRB).

This protocol has been submitted by the investigators to the Institutional Review Board (Committee on Ethics) of the Academic Medical Center. The study could proceed without approval as the IRB considered the P.S.S. treatment protocol to be within the limits of protocolled medical practice.