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Assessing the efficacy of a modified surgical technique in the treatment of unstable sacral fracture

Submission date
30/12/2018

Recruitment status
No longer recruiting

Registration date
24/01/2019

Overall study status
Completed

Last Edited
27/02/2023

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Background and study aims
It remains a complex and challenging problem to stabilize vertical unstable sacral fractures. Here, we describe a modified triangular osteosynthesis protocol to fix the sacral fractures. Our aim was to evaluate clinical effects by using this modified technique.

Who can participate?
Patients with sacral fractures

What does the study involve?
All participants received the same treatment, the modified triangular osteosynthesis protocol was applied in every case and done by one doctor team; data before and after operation for every case was collected and compared.

What are the possible benefits and risks of participating?
The technique can fix vertical unstable sacral fractures that have achieved faster and sufficient stability and reduce the discomfort of patients. There are risks associated with the operation and anaesthesia.

Where is the study run from?
Department of Orthopedics, Affiliated Dongfeng Hospital, Hubei University of Medicine.

When is the study starting and how long is it expected to run for?
The overall trial started on June 10, 2010. We observed the cases from Oct 7, 2010 to Dec 30, 2017.

Who is funding the study?
The cost for the study was in part paid by the local medical insurance and the grants from the grants from the Jingchu Program for Excellent Talents, the Provincial Educational Board of Hubei in 2017 (NO. 54), the Scientific and Technological Project of Shiyan City of Hubei Province (NO.14K72) and Teach & Research Program of Hubei University of Medicine (NO. 2017036).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
201008002

Study information

Scientific Title
A modified triangular osteosynthesis protocol for the rod and pedicle screw of vertical unstable sacral fracture: an observational case series.

Acronym
N/A

Study objectives
The aim of the present study was to analyze the clinical effect of a modified technique (vertical and transverse bringing-fixation with the rod and pedicle screw system) for sacral fracture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of Sinopharm Dongfeng General Hospital, 10/08/2010, ref. 201008002.

Study design
Observational case series

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Sacral fracture

Interventions
Following initial treatment, when the patient's condition was sufficiently improved to allow surgical intervention, the current surgery was performed. This is a single step procedure, which took an average lag time of 6 - 8 days that spans the initial trauma and definite operation. The anterior external fixation was then removed. The posterior pelvis injury was addressed first with reduction and stabilization. The patient was placed in the prone position; an image boost was used during the course of operation (conventional C-arm fluoroscopy).

Two initial skin incisions were made for all cases. A longitudinal and curved approach to the lumbosacral spine was made on a posterior median linebetween the L4, L5 and iliac bone through the posterior-superior-iliac-spine; another one was made on a line along the contralateral iliac bone through PSIS. To allow a deeper seating of the screw head and prevent prominence of the metal work under the soft tissues, we made a bone window with a reamer in the bilateral iliac bone. A third paravertebral incision was made to perform sacral laminectomy when the patient was accompanied with pre-operative perineal neurological impairment.

We used an USS rod and pedicle screw system (USS Fixateur Interne) during the procedure. First, pedicle screw insertion points were identified. After tapping, two pedicle screws were inserted into the pedicle of L4 and L5. The other three pedicle screws were inserted into the ilium between the inner and outer cortices. Then a straight rod was pre-curved to a L-shape with the angle according to screws position in L4L5 pedicle and iliac bone through the PSIS, that consisted of a vertical fixation. A straight rod was connected in situ between bilateral parallel iliac screws through the PSIS that consisted of a transverse fixation. To reduce the fracture, screws were used as "joysticks" and a manipulator between the two screws was used. We loosened and tightened one screw that followed with a compressor to perform the reduction as well as manual forces to distract the ilium both posteriorly and caudally. The correct reduction of sacral fractures was confirmed posteriorly by palpation of the symmetrical positions of the bilateral PSIS and the image boost. The pedicle screw and the iliac screw were finally connected with the rod system.

After copious irrigation, the surgical wound was closed on two suction drains. Next, the disrupted symphysis pubis or fractures of the pelvic rami was performed in the supine position using a dynamic compression plate, fixation depending on displacement level of anterior pelvic ring injury.

Total duration of observation: from October 7th in 2010 to December 30th in 2017.
Total duration of follow-up: from November 1st in 2010 to December 30th in 2017.

Intervention Type
Procedure/Surgery

Primary outcome measure
1.The following were measured post-operatively by reviewing patient and operation notes:
1.1. Time from admittance to surgery (delay days)
1.2. Duration of surgery
1.3. Blood loss volume and blood vessel
1.4. Nerve injury

Secondary outcome measures
1. The following were measured post-operatively by reviewing patient and operation notes:
1.1. Follow-up duration
1.2. Neurological deficit
1.3. Skin lesion
1.4. Deep infection when reviewing patient and operation notes.
2. The following were measured using X-ray and CT imaging:
2.1. Tenderness
2.2. Loss of reduction
2.3. Fracture heal

Overall study start date
10/06/2010

Completion date
30/07/2017

Eligibility

Key inclusion criteria
1. Vertical unstable sacral fractures
2. Neural injury with associated intraforaminal debris

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
28

Total final enrolment
28

Key exclusion criteria
1. Soft tissue defects that prevent operation zone coverage (the lumbosacral spine zone)
2. L4, L5 and iliac bone fractures through the insertion points of rod and pedicle screw system
3. Pathological fracture caused by osteoporosis or tumor
4. Follow-up less than 10 months.

Date of first enrolment
10/08/2010

Date of final enrolment
30/07/2016

Locations

Countries of recruitment
China

Study participating centre
Dongfeng Hospital of Hubei University of Medicine
Department of Orthopedics, Dongfeng Hospital of Hubei University of Medicine
Shiyan, Hubei Province
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442008

Sponsor information

Organisation
Affiliated Dongfeng Hospital, Hubei University of Medicine

Sponsor details
Affiliated Dongfeng Hospital, Hubei University of Medicine
Shiyan, Hubei Province
China
442008

Sponsor type
Hospital/treatment centre

ROR

https://ror.org/04fb6qy86

Funder(s)

Funder type
Government

Funder Name
The Jingchu Program for Excellent Talents, the Provincial Educational Board of Hubei in 2017 (NO. 54), China

Funder Name
The Scientific and Technological Project of Shiyan City of Hubei Province (NO.14K72) , China

Funder Name
The Teach & Research Program of Hubei University of Medicine (NO. 2017036), China

Results and Publications

Publication and dissemination plan
We will publicate our observation as soon as possible.

Intention to publish date
30/12/2018

Individual participant data (IPD) sharing plan
The data for the current study has been stored in medical records room of Affiliated Dongfeng Hospital of Hubei University of Medicine. The hospital is located in Shiyan 442008, Hubei, China. The data will be shared for scientific research upon request, but patient's information should kept anonymous. We obtained consent from participants and are aware of ethical restrictions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		07/01/2019	24/01/2019	No	No
Results article		01/06/2021	27/02/2023	Yes	No