Intra-operative application of ultrasonography combined with limited radiography for the treatment of supracondylar humerus fractures in children: a randomized controlled trial

Yuan Li, Zongyi Wu, Xianhong Yi, Chenghuang Mao, Guangkui Yan, Mingqiao Fang, Tianlong Pan, Ruibo Zhu, Jingdong Zhang

Department of Orthopaedics Surgery, The Second Affiliated Hospital and Yuying Children’s Hospital of Wenzhou Medical University, Wenzhou, Zhejiang Province, People’s Republic of China

Abstract

Aims: To introduce a new method of intra-operative application of ultrasonography (US) combined with limited radiography to treat supracondylar humerus fractures in children and evaluate its effect on radiation protection. Material and methods: Fifty patients were randomly divided into the radiography-only group (RO group, n = 22) and the US combined with the limited radiography group (UR group, n = 28). US was performed to evaluate fracture displacement and to guide reduction in the UR group. The primary outcome measures were the average number of radiography instances and the quantitative value of radiation emission. Secondary outcome measures were length of hospital stays, loss of range of motion, loss of carrying angle, loss of Baumann angle, fracture healing time, pin site infection, compartment syndrome, cubitus varus, cubitus valgus, and iatrogenic ulnar nerve injury. Results: Average number of radiography instances and quantitative value of radiation emission in the UR group decreased compared with the RO group (p<0.05). There were no significant differences between the groups regarding mean time to surgery, the average length of hospital stays, average surgery time, radiological union time, Flynn grade, or loss of Baumann angle. Pin site infection was seen in one patient in the RO group and two patients in the UR group. No other complications occurred. Conclusion: Intra-operative application of US combined with limited radiography decreases radiation exposure during treatment of supracondylar humerus fractures in children without compromising the therapeutic effect. Keywords: supracondylar humerus fractures; ultrasonography; radiography; radiation exposure; children

Introduction

Supracondylar humerus fractures are the most common fractures around the elbow in children, constituting 60–65% of all fractures, with a peak incidence between 4 and 7 years of age [1]. According to Gartland’s classification and Wilkins Modification of Gartland’s classification, types 2b, 3a and 3b are generally treated surgically [2,3]. With the popularization of closed reduction and percutaneous pinning in treating supracondylar humerus fractures, problems such as radiation exposure appear, threatening the patients’ and medical staff’s health. The risk of cancer mortality was estimated at 5% per Sievert for adults and up to 9.1% for a 10-year-old child, with increased risk for younger children [4-7]. This finding suggests that children are more sensitive to radiation exposure. Furthermore, it is difficult for surgeons to grasp the position and direction of internal fixation accurately when treating young children; therefore, the number of radioscopies may increase.

Furthermore, the younger the child is, the closer the body (especially the radiation-sensitive glands) to the radioactive source; therefore, radiation exposure may be higher. Orthopedic surgeons are five times more likely to develop cancer in their lifetime compared to other health-care workers due to occupational radiation exposure [8]. Increasing the distance between surgeon and the radio-
active source is the most crucial protective measure [9]. However, the surgeon’s hands are often directly exposed to the rays and cannot be effectively protected due to the need to maintain the fracture position during the operation. Therefore, the risk of basal cell carcinoma in the fingers of orthopedic surgeons has increased, even requiring amputations [10]. Although protective lead apparel, thyroid shields and lead goggles are routinely used, radiation exposure cannot be avoided altogether. In addition, these things have a useful life; if the hospital does not replace them in a timely fashion, the surgeon’s protection will be reduced. For these reasons, it is essential to identify radiation-free methods that can guide the reduction of the fractures and monitor the position of the fragments in real-time.

Ultrasonography (US) is a radiation-free method that is used to diagnose diseases of the musculoskeletal system. It is characterized by real-time imaging, planar capabilities, cost-effectiveness, patient comfort, noninvasiveness, portable and absence of radiation exposure. US dynamically displays and evaluates the anatomical relationships between nerve and muscle in the elbow joint [11] and is a reliable method to examine the elbow joint, including the humeral-ulnar and the humeral-radial joint [12,13]. Our previous work demonstrated that the application of intra-operative US allowed monitoring of the reduction of femoral shaft fractures and guiding the insertion of elastic stable intramedullary nails [14]. Based on the previous studies, we aimed to study the intra-operative application of US combined with limited radiography to treat supracondylar humerus fractures in children.

Material and methods

Study design

The trial was a randomized controlled trial in which children with type 3 supracondylar humerus fractures were enrolled and treated by closed reduction and percutaneous pinning with the assist of intra-operative application of US or not. The trial was a single-center study conducted by a team of physicians experienced in pediatric orthopedic surgery, US or statistical analysis. Recruitment, randomization, surgery, follow-up, data collection, and statistical analysis were completed by different physicians. Written informed consent was obtained from all children’s parents or guardians following the World Medical Association Declaration of Helsinki. The Ethics Committee of the hospital granted permission for the use of ultrasonography during the surgeries.

Patient recruitment and sample size calculated

An independent staff member who did not participate in other study processes was appointed to recruit patients. Inclusion criteria were type 3 supracondylar humerus fractures in children according to Garland’s classification. At the time of consultation, there had been no more than 24 hours after the injury. Patients with multiple injuries, neurovascular damage, open fractures, cerebral palsy, previous injury of the homolateral elbow or other medical contraindications to surgery were excluded. Patients present at the outpatient or emergency of the hospital from January 2018 to December 2018 were potential candidates. Patients who do not meet the criteria or refuse to participate in the study were excluded. Furthermore, patients who were suspended from participating in the trial or follow-up less than 12 weeks were also excluded. Finally, a total number of 50 patients were included in the study. A diagram of recruitment is displayed in figure 1.

Randomization

Randomization was done after the patient was under general anesthesia in the operating theatre, with the treating surgeon opening the assigned envelope. Before trial recruitment, randomization was performed for the expected trial population using a computer-generated list. Assigned allocation, US+radiography (UR) or radiography only (RO) group, was sealed in individual coded envelopes. The envelopes could not be opened until the patient was under general anesthesia.

Blinding

The recruiter did not take part in the randomization, surgery, data collection, or statistical analysis. Patients were blinded to the primary choice of treatment but not to the treatment itself. Randomization and allocation were performed by the treating surgeon after induction of general anesthesia. Data collection during the surgery was not blind. Data collection after the surgery was performed by an independent physician and was blind. Statistical analysis was performed by an independent statistician who did not participate in other study procedures.
Intervention
Surgeries were performed by the same surgeons experienced in pediatric orthopedic surgeries and US in both groups. All surgeries were performed within 24 hours of emergency visits in both groups.

RO group
Surgeries in the RO group were performed as per routine. Briefly, after the induction of general anesthesia, the patient was maintained in the supine position with the elbow placed on the plate of the image intensifier. After preoperative preparation, longitudinal traction was applied first with the forearm supinated to dislodge the fracture and gain length. Lateral extrusion and rotation of the distal fragment were subsequently performed to reduce lateral displacement and rotational malalignment. Then the elbow joint was flexed to restore the displacement on the sagittal plane. Radiography was then performed to judge the position of the fragments. Restoration and radiography was repeated until the reduction was satisfactory. Percutaneous lateral pinning using two or three diverging Kirschner wires was performed subsequently. When the position of the Kirschner wires was not satisfactory, or the distal fragment was displaced again, restoration, radiography and adjustment of pinning were required until the fracture reduction, and fixation was satisfactory. During the process, intra-operative radiography could be repeated many times.

UR group
Surgeries of the UR group are described below. To clarify the feasibility of the technology to the greatest extent possible, we used images from more than one patient. For the use of intra-operative ultrasonography, an M-Turbo, Portable Color Doppler Ultrasound System (SonoSite Co., America) with linear transducer of 7.0 to 11.0 MHz was employed. The frequency and depth were adjusted to obtain clear images. A sterile endoscope cover (Yafu Biological Technology Co., Ltd. Guangzhou, Guangdong Province, China) was used to coat the transducer, and sterile gel (Lijun Essence Pharmaceutical Co., Ltd. Xian, Shanxi Province, China) was used as a coupling agent to ensure sterile conditions. Pre-operative radiographs were carefully reassessed before the surgery (fig 2). After preoperative preparation, the preliminary reduction was performed according to the preoperative radiographs and the elbow was flexed maximally subsequently. Nevertheless, displacement of the fracture usually remained. Then, intra-operative US was performed to evaluate the displacement of the fracture and the images were used as the references for further reduction. The nature of cortical bone causes the reflection of ultrasound waves and produces hyperechoic reflections from the bone surface. The position of the discontinuous hyperechoic reflection indicates the fracture site. The depth of the hyperechoic reflection on the images indicates the distance between the fragments and transducer. Coronal scanning with the transducer placed longitudinally on the lateral elbow was first performed. The distal fragment deeper than the proximal fragment on the image indicates the medial displacement of the fracture (fig 3). By contrast, the two fragments adjacent at the fracture site, the apex against the transducer indicated hyperextension of the fracture (fig 5). To evaluate malrotation of the distal fragment, the transducer was placed longitudinally on the posterior lateral and posterior medial of the elbow to scan the distal fragment.
The increase of the depth on the lateral part with the decrease of the depth on the medial part indicated pronation of the distal fragment (fig 6). By contrast, the increase of the depth on the medial part with the decrease of the depth on the lateral part indicated supination of the distal fragment. Two transducers scanning was even better for evaluating malrotation. After ascertaining the displacement situation, reduction of the fracture and ultrasound scanning was performed repeatedly until the displacement was corrected (fig 7). Then, radiography was performed to confirm the reduction was satisfactory and percutaneous lateral pinning using two or three diverging Kirschner wires was performed subsequently. Radiography was performed for a final check before the finish of the surgery (fig 8). The subsequent process was performed as usual.

**Follow-up**

Follow-up was conducted at 2 and 4 weeks and then every other month to record the clinical results, radiographic results and complications.

**Outcome measures**

The primary outcome measures were the average number of radiography instances and the quantitative value of radiation emission. Radiography instances of each surgery were recorded. The average number of radiography instances of the two groups was calculated. The quantitative value of radiation emission of each surgery was calculated by recording the value of radiation produced by each radiography. Secondary outcome measures were length of hospital stays; clinical results such as excellent, good, fair or poor; radiographic results such as loss of Baumann angle, fracture healing time; complications during the follow-up. Age, gender, the injured side, time to surgery between the groups were also compared. Hospital stays were calculated as the length from admission to discharge. Clinical results were graded as excellent, good, fair or poor according to the loss of range of motion and loss of carrying angle using the criteria of Flynn et al [15]. Loss of Baumann angle was calculated through the anteroposterior (AP) view. Loss of Baumann angle and clinical results were assessed at 12 weeks to get a true AP radiograph when most of the elbow could be fully extended, rather than at 4 weeks, when the elbow was stiff, which could influence the assessment of loss of ROM and loss of carrying angle. Radiographic fracture healing time was defined as continuous osteotylus forma-
tion at the fracture site and the fracture line become indefinite on the radiograph. A complication was defined as any adverse event for which additional treatment was required. Complications included compartment syndrome, cubitus varus, cubitus valgus, and iatrogenic ulnar nerve injury.

Statistical analysis
Statistical analysis was performed using Pearson’s chi-square test and the Student’s t-test. The normality of the data was tested and obeyed normal distribution. All p-values were three-tailed, and the significance level was set at 0.05. The analyses were performed using the SPSS software ver. 18.0 (SPSS Inc., Chicago, IL, USA).

Results
In the RO group, the number of randomly assigned participants was 26, and in the UR group, the number was 34. Twenty-two patients received intended treatment and were analyzed for the primary outcome in the RO
group; in the UR group, 28 patients received intended treatment and were analyzed for the primary outcome. Four patients were excluded before analysis in the RO group because one patient withdrew informed consent and for three patients, follow-up less than 12 weeks. In the UR group, six patients were excluded before analysis; three withdrew informed consent and three follow-ups were less than 12 weeks.

All cases included for statistical analysis were followed up for at least 21 weeks. The mean duration of follow up, demographic data, mean time to surgery, average surgery time and average length of hospital stays in the two groups are detailed in Table I.

Reduction with the assistance of US decreased radiation exposure. The average number of radiography, quantitative value of radiation emission, evaluation following Flynn criteria, loss of Baumann angle, fracture’s radiological union time and pin site infections in the two groups are listed in Table I.

No patient developed compartment syndrome, cubitus varus, cubitus valgus, or iatrogenic ulnar nerve injury among the 50 patients, and no patient underwent repeated surgery to treat the fracture.

Discussion

The use of mobile radiography for intra-operative imaging is essential for treating supracondylar humerus fractures by closed reduction and percutaneous pinning. However, obtaining intra-operative images in real time comes at the cost of radiation exposure to patients and surgeons. It is widely accepted that surgeons exposed to low-dose radiation for long periods and children who have higher tissue radiosensitivity face long-term health risks. Current strategies to reduce radiation exposure include the application of the inverted C-arm and mini-C-arm, surgeon control of image acquisition, pulsed fluoroscopy and image collimation, use of protective lead apparel, thyroid shields and lead goggles for both patients and surgeons, greater surgical experience and proper C-arm calibration [16-18]. It is worth mentioning that the use of intra-operative US was intended to reduce radiation exposure rather than a substitute for all intra-operative radiography. In addition to reducing radiation exposure, intra-operative US could also be used to evaluate the integrity of the posterior cartilage hinge. An intact cartilage hinge is helpful during the reduction of the fracture, and matching between the cartilage hinge and the bone surface is an indirect indication of fracture reduction. Moreover, when the fracture line extends from medial superior to lateral inferior, medial pinning may be applied, and intra-operative US could be used to monitor the position of the ulnar nerve to avoid iatrogenic injury.

The application of US in surgery is used to determine the position of the fragments and the process together with reduction may be performed repeatedly during the surgery. Therefore, the repetitive process of restoration and radiography in the UR group was changed to a repetitive process of restoration and ultrasound scanning. Intra-operative application of US dramatically reduces the number of radioscopies in this process. Type 3 humeral supracondylar fractures are highly unstable. Even if the reduction is satisfactory initially, the fragment may be displaced again during the percutaneous pinning. Therefore, after initial fixation, US can be used to evaluate the fragment position instead of radiography. Once the distal fragment is found to be displaced, the Kirschner wires need to be withdrawn and restoration and US performed again. US can replace radiography in this process again to further reduce radiation exposure.

In the present study, the primary reduction was performed according to pre-operative radiographs and the
elbow was subsequently placed in hyperflexion to stabilize the fracture. As a result, US performed on the anterior elbow was limited. However, scanning the posterior and lateral elbow was sufficient to evaluate the displacement on a single plane. Reduction of the fracture manifested as continuous cortical bone with a smooth contour. According to the position of the distal fragment on the image (above or below the proximal fragment), we can determine whether the distal fragment is close or away from the transducer. According to the transducer position (lateral or medial side), we can determine whether the distal fragment is lateral or medial displacement. Determination of torsional malalignment in all kinds of fractures is difficult sometimes under intra-operative radiography. Ehrenstein T et al proposed using a modified transducer attached with a goniometer to assess torsional deformity [19]. However, the modified transducer and goniometer are not always available in every hospital. The method present in the study can also effectively determine the situation of rotation. This method may be easier and more intuitive when two transducers are used simultaneously.

The results of our study suggested that the transducer did not extend the length of hospital stays, surgery time or bone union time, with an apparent decrease in radiation exposure. The functional outcomes and occurrence of complications were similar between the groups. The absence of other complications may be related to the small number of cases rather than a sign that the level of our surgeons is exceptionally high or that the use of the technique will decrease complications.

All surgeries were performed within 24 hours after the emergency visit. This was done to prevent compartment syndrome and reduce anxiety on the part of the patients and their guardians. Moreover, the swelling of the elbow increases the difficulty of reduction and influences the ultrasound scanning, the transducer requiring a delicate and smooth operation to optimize imaging.

Furthermore, it also requires clear cognition of ultrasound images. Surgeons should be capable of identifying normal tissues and the interference caused by hematomas and bone fragments. Three-dimensional imagination and integration capabilities are also required to provide an optimal grasp of the overall situation of the fracture. As long as repeated training is performed, this technique is not difficult to perform.

There were several limitations in the study, including the small number of cases in each group. The study was a single-center trial; the results may be influenced by the level of surgeons in the hospital. The clinical results were graded as excellent, good, fair, or poor according to the criteria of Flynn et al [15]. Nevertheless, whether the patient returned to the same function as before the fracture remains unknown. Surgeons were not blinded to the treatment process, which may influence the result of radiation exposure. However, studies will be continued further to demonstrate the feasibility and advantages of the technique.

Conclusions

The application of intra-operative US for treating supracondylar humerus fractures can decrease radiation exposure without reducing therapeutic efficacy.

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Conflict of interest: none.

References

1. Beaty JH, Kasser JR. Fractures about the elbow. Instr Course Lect 1995;44:199-215.
2. Gartland JJ. Management of supracondylar fractures of the humerus in children. Surg Gynecol Obstet 1959;109:145-154.
3. Shenoy PM, Islam A, Puri R. Current Management of Paediatric Supracondylar Fractures of the Humerus. Cureus 2020;12:e8137.
4. Giachino AA, Cheng M. Irradiation of the surgeon during pinning of femoral fractures. J Bone Joint Surg Br 1980;62-B:227-229.
5. Martus JE, Hilmes MA, Grice JV, et al. Radiation Exposure During Operative Fixation of Pediatric Supracondylar Humerus Fractures: Is Lead Shielding Necessary? J Pediatr Orthop 2018;38:249-253.
6. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP publication 103. Ann ICRP 2007;37:1-332.
7. National Research Council of the National Academies. Health risks from exposure to low levels of ionizing radiation: BEIR VII Phase 2. The National Academies Press, Washington, DC. 2006. doi:10.17226/11340.
8. Mastrangelo G, Fedeli U, Fadda E, Giovanazzi A, Scozzato L, Saia B. Increased cancer risk among surgeons in an orthopaedic hospital. Occup Med (Lond) 2005;55:498-500.
9. Mehlman CT, DiPasquale TG. Radiation exposure to the orthopaedic surgical team during fluoroscopy: “how far away is far enough?”. J Orthop Trauma 1997;11:392-398.
10. Hafez MA, Smith RM, Matthews SJ, Kalap G, Sherman KP. Radiation exposure to the hands of orthopaedic surgeons: are we underestimating the risk? Arch Orthop Trauma Surg 2005;125:330-335.
11. Radanovic G, Vlad V, Micu MC, et al. Ultrasound assessment of the elbow. Med Ultrason 2012;14:141-146.
12. Barr LL, Babcock DS. Sonography of the normal elbow. AJR Am J Roentgenol 1991;157:793-798.
13. Davidson RS, Markowitz RI, Dormans J, Drummond DS. Ultrasonographic evaluation of the elbow in infants and young children after suspected trauma. J Bone Joint Surg Am 1994;76:1804-1813.

14. Wu ZY, Yi XH, Li YA, et al. Decreased Radiation Exposure Using Ultrasound-Assisted Reduction and Fixation of Femoral Shaft Fractures in Children: A Pilot Study. Ultrasound Med Biol 2020;46:3154-3161.

15. Flynn JC, Matthews JG, Benoit RL. Blind pinning of displaced supracondylar fractures of the humerus in children. Sixteen years’ experience with long-term follow-up. J Bone Joint Surg Am 1974;56:263-272.

16. Schmucker A, Chen R, Vachhrajani S, Martinek M, Albert M. Radiation exposure in the treatment of pediatric supracondylar humerus fractures. Arch Orthop Trauma Surg 2020;140:449-455.

17. Tremains MR, Georgiadis GM, Dennis MJ. Radiation exposure with use of the inverted-c-arm technique in upper-extremity surgery. J Bone Joint Surg Am 2001;83:674-678.

18. Giordano BD, Ryder S, Baumhauer JF, DiGiovanni BF. Exposure to direct and scatter radiation with use of mini-c-arm fluoroscopy. J Bone Joint Surg Am 2007;89:948-952.

19. Ehrenstein T, Rikli DA, Peine R, et al. A new ultrasound-based method for the assessment of torsional differences following closed intramedullary nailing of femoral fractures. Skeletal Radiol 1999;28:336-341.