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to the standardized radiography for fractures. Ultrasonography could be particularly

Objective: We studied the characteristics and risk factors involved in neon

Conclusions: The majority of clavicular fractures occur in normal n

Keywords: Newborn; Clavicular Fracture; Ultrasound

Introduction

Birth trauma is one of the main causes of neonatal morbidity and mortality [1,2]. Fracture of the clavicle occurs in up to 4.5% of vaginal births and accounts for approximately 90% of all obstetrical fractures with equivalent sex and side distribution [3-5]. e clavicle is easily fractured because of its subcutaneous, relatively anterior location and frequent exposure to transmitted forces. Also, the lack of muscular and ligamentous support makes it more vulnerable to injury [6]. e diagnosis is suspected by clinical examination and con rmed by plain radiographs [7]. Although displaced clavicular fractures are relatively easily diagnosed clinically, non-displaced fractures may be apparent only a er callus formation or if all neonates are subjected to radiography or ultrasonography, or multiple physical examinations [8,9]. A fractured clavicle in a newborn can o en be di cult to diagnose because it is o en asymptomatic and can also be confused with other common diagnoses such as brachial plexus palsy, congenital pseudo-arthrosis, and congenital muscular torticollis [10]. e most common sign is lack of active, spontaneous movement of the a ected upper extremity arm. Crepitus, a palpable bony abnormality, or discoloration over the fracture site and asymmetric Moro re ex may be observed [11]. Neonatal clavicle fractures generally heal uneventfully, can be treated non-operatively and have an overall excellent prognosis [4]. An apparent fracture of the clavicle at birth does not always indicate birth trauma, since neonatal injury can also occur a er normal vaginal delivery or cesarean section in the absence of an obvious traumatic delivery. It has been suggested that some clavicular fractures may be the result of preexisting fetal conditions rather than any unusual forces exerted at delivery [1,5,9,12]. Syndromes involving chromosomes 11, 18, and 22 have been reported with congenital defects of the clavicle, and congenital pseudarthrosis of the clavicle may be present at birth [13]. Many studies were performed to clarify the possible risk factors

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for birth fractures of the clavicle [4,5,12,14,15]. In recent years, US has already been used to diagnose neonatal clavicle fractures [8]. Because US may show poorly ossi ed neonatal bones better than radiographs, displaying indirect signs of fracture, such as signs of hematoma or detachment of the periosteum, evaluation of so tissue such as muscle edema, tendon and joint functions, localizing the interposition of so tissues between fracture fragments preoperatively and because it lacks ionizing radiation; this technique seems to be an excellent alternative to radiography [16]. e aim of the current study was to analyze the incidence of fracture of clavicle in newborn infants following normal delivery, the associated risk factors and the evaluation of the accuracy of ultrasonography (US) in diagnosing this fracture.

Patients and Methods

is observational prospective study was conducted in AL-Kha i Joint Operation (KJO) Hospital, Kingdom Of Saudi Arabia during the period from August 2013 to September 2016. During this period, there were no changes in the institutional policy regarding management of delivery or the criteria for diagnosis of neonatal clavicular fracture. From 7560 deliveries during the period of the study (5120 vaginal deliveries and 2440 CS), 48 cases diagnosed clinically and radiologically with fracture clavicle of them 43cases were included in our study as we excluded 2 cases delivered by cesarean section, one case with osteogenesis imperfect and 2 patients with multiple congenital anomalies.

Inclusion criteria: Database of the Departments of Neonatology and Obstetric was reviewed for all cases delivered by spontaneous vaginal delivery in the occipito-anterior position and singleton-term pregnancy. Exclusion criteria: Babies delivered by CS and those with multiple deformities

All variables were compared with a control group of an equal number of healthy infants born immediately before or a er each a ected infant and delivered by the same obstetrical team.

All newborns included in the study undergo routine physical examination twice during the rst 24 h of birth and later before discharge from the hospital. In the postnatal period, the infants were followed up at the neonatology outpatient clinic for various problems including monitoring for jaundice and feeding problems.

Diagnostic criteria for neonatal clavicular fracture include inspection for asymmetry of the clavicular bones, absence of the supraclavicular notch and local edema or hematoma; by palpation for crepitus and local tenderness re ected by the baby's cry.

All the clinically suspected cases of clavicular fracture were con rmed diagnosis by plain-X ray. Blind ultrasonography (US) was done to all con rmed cases to evaluate its accuracy in diagnosing this fracture

Data collected for analysis included the following:

Prenatal history: Maternal age, height, weight, parity, presence of gestational diabetes and sonographic fetal weight estimation and gestational age.

Perinatal history: Premature rupture of the membranes, shoulder dystocia, induction of labor, duration of second stage de ned as the time from full dilatation to delivery, the need for oxytocic augmentation of uterine contractions, use and type of analgesia or anesthesia and performance of episiotomy.

Postnatal examination: Apgar score at 1 and 5 minutes, infant sex, measurements including birth weight, length and head circumference, presence of neonatal morbidity including Erb palsy and birth trauma

Radiological assessment:

Conventional standard radiographs were done to all cases suspected clinically to have clavicular fracture. Real-time ultrasound examination was carried out in all suspected cases by radiology consultant with a standard US machine (Samsung Medison SonoAce X8, Korea) equipped with a small 7.5 MHz linear array Transducer using longitudinal views aligned to the clavicle. Discontinuity, axial deviation, periosteal lesions, hematomas and so -tissue changes were recorded. During the examination, the infant was laid on his or her back so that the operator was looking down on the shoulder. e mother held the arm. Both shoulders were examined, starting with the clinically una ected side. Callus, as a sign of bone healing, could be seen with time in all patients. e mean age of the infants at the time of ultrasound examination was two days and when a fracture was detected, the infant was re-examined clinically and by ultrasound at six weeks of age by orthopedic physician.

Statistical Analysis

Data were presented as mean ± standard deviation (X ± SD) or percentage (%). e means of two groups were compared using student's t test. e odds ratio (OR) and 95% con dence interval (95% CI) were calculated for clavicular fracture susceptibility in relation to the studied risk factors. All data were analyzed using Epi Info statistical so ware, version 6.2 (WHO, Geneva, Switzerland) and Statistical Package for Social Sciences, version 22.0 (IBM Corp., Armonk, NY, USA).

P value <0.05 was considered statistically signi cant.

Results

Our study enrolled 43 cases delivered vaginally (0.84 % of all vaginal deliveries) with con rmed clavicular fracture clinically and radiologically. Twenty- ve patients had fracture in the right side while 18 were on the le side with the medial third fracuture a ected in all patients. Of these patients 20 were females (46.5%) and 23 were male (53.5 %). e control group were age, sex, and ethnicity-matched to patients (P>0.05).

e peripartum characteristics of the studied groups are shown in Table 1. ere were no statistically signi cance di erence between cases and controls groups regarding maternal age (30.9 ± 7.4 versus 31.2 ± 5.5 years), parity (2.2 ± 1.4 versus 2.1 ± 1.8 deliveries) and materna weight (66.7 ± 9.2 versus 68.3 ± 8.5 kg). On the other hand, signi cant di erences were found between the 2 groups regarding maternal height, the duration of second stage of labor, peripartum sonographic fetal weight estimation and neonatal birth length (P<0.05) (Table 1).

Table 2 demonstrates the prevalence of the risk factors for neonatal clavicular fracture in patients and controls. e risk of clavicular fracture was signi cantly higher among patients with birth weight greater than 4000 g (OR: 4.2; 95% CI: 1.25 - 14.27; P=0.02), estimate gestational age greater than 40 weeks (OR: 4.04; 95% CI: 1.026 - 15. P=0.045), with shoulder dystocia delivery (OR: 7.05; 95% CI: 1.46 - 34.08; P=0.01), and those with history of prolonged second stage of labor (OR: 5.4; 95% CI: 1.1 - 26.8; P=0.038). However, we did not observe any signi cant association of nulliparity and instrumental delivery with fracture clavicle. Unfortunately, one baby was diagnosed with Erb's palsy that complicated clavicular fracture with partial

		Radiographs		Sensitivity (95%CI)	**Specifcity** (95%CI)	PPV (95%CI)	NPP (95%CI)	Accuracy (95%CI)
		True Fracture	True Non Fracture					
86	Fracture YH WHVW	WUXH YH IDOVH YH						
	Non fracture YH WHVW	IDOVH YH WUXH YH						
86 8OWUDVRXQG 339 3RVLWLYH 3UHGLFWLYH 9DOXH 133 1HJDWLYH 3UHGLFWLYH 9DOXH								

Table 4: 3HUIRUPDQFH RI 86 LQ WKH GHWHFWLRQ RI FODYLFXODU IUDFWXUHV FRPSDUHG

Figure 1: 6KRZLQJ D IUHVK IUDFWXUH ZLWK LQWHUUXSWLRQ RI FRUWLFDO DUURZV

Figure 2: 6KRZLQJ KHDOHG IUDFWXUH ZLWK FDOOXV IRUPDWLRQ RI baby after 3 weeks.

Although the fracture clavicle generally heals well without long-term sequelae, our study revealed one baby out of 43 cases of clavicular fracture (2.3%) with Erb's palsy. In a 5-year retrospective study involving 5847 live births, one of the 60 (1.7%) newborns with clavicular fracture had Erb's palsy [21]. In another retrospective review of 21,632 live births, clavicular fracture was found in 58 newborns, three (5.2%) of whom had concurrent Erb palsy with good recovery [22]. In a survey of 11,636 neonates admitted to the neonatal nursery, 2.29% had clavicular fracture, and 0.44% had Erb's palsy [4]. As palsy is not our concern in this study, and this incidence may not be true for Erb's palsy because of small sample size.

A second stage of labor of more than 20 minutes has been associated with shoulder dystocia and possibly birth injuries [23]. In our study, there is positive correlation between the duration of second stage of labor and the incidence of clavicular fracture. ese ndings were going with the study of Kaplan et al. in which clavicular fracture rate was 1.65% [5], and they found that several variables including duration of second stage of labor, peripartum sonographic fetal weight estimation and neonatal birth length were positively correlated with neonatal clavicular fracture Regarding maternal height, our study revealed that short stature of the mother is another risk factor for clavicular fracture, which can be explained by that low maternal height, is associated with contracted pelvis and obstructed labor with increased incidence of birth trauma and clavicular fracture. In a study done by Gudmundsson et al. [24] they found a highly signi cant relationship between newborn birth weight and maternal height and the frequency of complications. e criterion for maternal short stature should be de nitely based on ethnic groups and must be categorized according to height percentile range rather than absolute height may allow comparison between di erent populations on the e ect on labor outcome [25]. In the present study, no association was found between maternal ages and weight with increasing the risk of neonatal clavicular fracture. Our results were going with the study of Poggi et al. who did not show an independent association between maternal obesity and neonatal birth injury [26]. However, Cedergren et al. found an association between morbidly obese mothers and increased risk of shoulder dystocia and birth injury [27]. Also a study by Ahn et al. concluded that major risk factor of clavicle fracture was vacuum delivery, mother with advanced age and high birth weight [28]. In the present study, we found that macrosomia, birth weight greater than 4000 g, and birth length of more than 52 cm were signi cantly associated with higher risk of neonatal clavicular fracture. Ozdener et al. showed that birth weight of over 3500 g and to a greater extent over 4000 g, were found to be an independent important factor associated with clavicle fracture [29]. Similar nding was reported by Lai et al. who showed macrosomic babies with birth weight of 4000 g to 4999 g has signi cant risk factor to developed lavicle fractures [30]. In our study, we found that the incidence of the neonatal clavicular fracture during labor was signi cantly increased with shoulder dystocia. Mehta et al. [23] concluded in their study that maternal obesity in their population was associated with an increased risk of neonatal injury a er shoulder dystocia. During 5-year period, they recorded 206 cases of shoulder dystocia out of 25995 deliveries. Of these, there were 19 cases of Erb's palsy and 6 cases of clavicul fracture. On the other hand, Beall and Ross [12] in their study was unable to demonstrate an association between clavicular fracture and shoulder dystocia., and reported in their study that neonatal clavicle fracture is associated with infant birth weight greater than 4 kg, but not with the occurrence of objectively de ned shoulder dystocia. Also, Beall et al. [31] found no correlation between clavicular fracture and shoulder dystocia and they reported that the association with shoulder dystocia may be false or intentional because of an increased tendency to report a shoulder dystocia in a delivery in which a birth injury has been

identi ed. In the present study, we found that increasing gestational age is also positively correlated with clavicular fracture. However, it loses its signi cance as risk factor when comparing with shoulder dystocia and birth weight. is result is going with results of Roberts et al. who found that gestational age is a risk factor for clavicular fracture at 40 and 41 weeks; and at 42 weeks or greater in strati ed analysis considering only gestational age [1]. In this study, we could not con rm that neonatal clavicular fracture was associated with instrumental deliveries (forceps or vacuum extraction). However, A study done by Lam et al. in which they reported 151 of 9540 (1.6%) clavicle fractures occur in their series and it was associated with increased incidence of instrumental delivery and shoulder dystocia [32]. Oppenheim also demonstrated that forceps deliveries and shoulder dystocia have a higher risk to develop clavicle fracture and brachial plexus injury [22]. In our series, we observed, no relation between maternal parity and neonatal clavicular fracture. Same results were found in Hassib et al. study who found an equal number of fracture clavicle cases in both multiparous and nulliparous [33]. On the other hand, Brown found that nulliparous has a higher risk compared to multiparous in developing neonatal clavicle fractured.

Recent studies have focused on the reliability and interest of US for the diagnosis of clavicular fractures in children [34]. One of the rst studies of the use of ultrasound for the diagnosis of fractures in the neonate was published by Katz et al, who studied Forty-one cases of clavicle fracture in newborn babies [35]. e babies were examined by both radiographic and ultrasonic methods and they concluded that no substantial di erence has been found between these two modalities. ey suggested that ultrasound should be the procedure of choice in the diagnosis of clavicle fracture. In our study, we examined the accuracy of US in diagnosing a neonatal clavicular fracture in comparison to X-ray. Overall, sensitivity, speci city, PPV, and NPV of on-site US were, respectively, for the presence (or absence) of fractures: 95.35% 97.5, 97.62% and 95.12%. US accuracy was 96.39%. One false positive and two false-negative US examinations were found. e three cases of disagreement (false-positives and false-negatives) needed second review of the ndings but we did not provide a second reviewer of our primary ultrasound. Our ndings are consistent with the results of the study done by balb et al. in which Forty-nine infants with clavicular fractures were examined radiologically and sonographically by independent examiners; and reported that US diagnosis of clavicle fractures in older children in an orthopedic clinic with high diagnostic accuracy 96% for US versus 91% for radiographs [36]. Also, Keith et al. in their study concluded that bedside ultrasound in the pediatric ED can accurately diagnose clavicle fractures when compared to plain radiographs [37]. However, radiography is still indicated in cases of neurological injury and related palsy and for congenital pseudarthrosis of the clavicle [11].

Conclusion and Recommendation

Our study has several limitations. First, our protocol was based on conventional radiography and not US as the gold standard for diagnosis of neonatal clavicular fractures. Second, all exams were done by trained musculoskeletal radiologists and it could be valuable to have a dedicated US course to evaluate the learning curve of junior radiologists. Finally, a larger patient population would probably have increased the statistical power of our results.

In conclusion, shoulder dystocia and large birth weight remains the main risk factors for obstetric clavicular fracture, although most birth clavicular fracture are unavoidable and unpredictable and the majority occur in uncomplicated normal vaginal deliveries. Given its diagnostic accuracy, minimal pain during examination, and lack of ionizing radiation. Bedside clavicular sonography, when performed by trained radiologists, is an excellent method for con rming a suspected fracture of the clavicle in the neonate when compared to radiography and thus US could be recommended for routine use in NICU in selected cases to avoid radiation exposure. Additional randomized clinical studies comparing US to radiography will be of great interest to consolidate clinical practice.

References

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