Morphometric Analysis of Clavicle and Its Medullary Canal: A Computed Tomographic Study

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Abstract

Background Intramedullary fixation is one of the common methods of treating clavicle fractures. Morphometric data of the clavicle and its medullary canal will help design a better device and surgical technique. Morphometric studies on clavicle are sparse; hence, this study.

Methods A 3-D reconstruction of 64 clavicles of 32 patients was done from computed tomography (CT) scan data of thorax obtained for the diagnostic workup of unrelated disease. The various dimensions of the clavicle and its medullary canal were measured. The narrowest part, point of change of direction of the medullary canal, curvatures of the clavicle, the position of the coracoid process, and the relation of these features to eight equally divided segments of clavicle were noted.

Results The average length of the clavicle was 142.5 mm. The average height and width of the narrowest part of the medullary canal were 2.4 mm and 2.5 mm, respectively, corresponding to segment 5 (S5) in more than half of the clavicles. The change of direction of the medullary canal and the medial edge of the coracoid process were corresponding to segment 6 (S6) in the majority of the clavicles.

Conclusion This computed tomographic study provides morphometric data of the clavicle applicable to intramedullary fixation of clavicle fractures. In the studied population, the clavicles were shorter, more curved, and had medullary canal dimensions less than 2.5 mm at the narrowest part. This may pose difficulties in intramedullary fixation. The coracoid process was a reliable anatomical landmark.

Keywords Clavicle fractures · Computed tomography · Medullary canal · Morphometry · Intramedullary device · Coracoid process

Introduction

Clavicle fractures are common, as they represent 2.6% of all fractures [1]. The commonest site of fracture is the middle third (82%) of the clavicle [2]. The Cochrane review of

surgical versus conservative interventions for treating fractures of the middle third of the clavicle is inconclusive [3]. Surgical treatment is gaining popularity because of the limitations of the conservative treatment [4]. Plating is one of the commonly used surgical techniques for treating these fractures. Extensive exposure, prominent implant, skin irritation, and increased incidence of infection are the disadvantages of plating [5]. Intramedullary (IM) fixation for fracture shaft clavicle may overcome these disadvantages. Intramedullary devices are gaining popularity in treating clavicle fractures [6, 7]. The intramedullary devices like Kirschner wires (K-wires), Rockwood or Hagie pins, intramedullary screws, titanium elastic nails have been tried in fixing clavicle fractures [8]. The peculiar features of the medullary canal of the clavicle are its progressively changing size and direction and its absence in the lateral end. Though the change of direction of the medullary canal happens both at medial and lateral curvature, the medial one does not pose difficulties in

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intramedullary fixation because of its wide dimensions. The lateral curvature poses difficulty in negotiating an intramedullary device because of its narrow dimensions. Hence, we have considered only the change of direction of the medullary canal in the lateral curvature. The data describing the morphometric parameters of the medullary canal of the clavicle are lacking in our population and a CT based study in this regard is needed. The study aims to find out the morphometric parameters of the clavicle and its medullary canal. The main objective of the study is to find out the narrowest part, the point of change of direction, and projection of the narrowest part of the medullary canal to the lateral end of the clavicle which may be the appropriate lateral entry portal for the intramedullary device. The consistency of the relation of the coracoid process to the above-mentioned objectives was analyzed which is an easily recognizable anatomical landmark even on a plain radiograph. Several anatomical studies of the clavicle have been performed in different populations in the past [9–13]. The extensive search of the literature did not find many CT based morphometric studies of the clavicle in Indian population.

Materials and Methods

The CT images included in this study were acquired from the database of the radiology department of BVVS S Nijalingappa Medical College and HSK Hospital and Research Centre, Karnataka (South India) from the year 2018 and standard protocol to de-identify the subjects were followed. Patients who had CT imaging of their thorax as part of their diagnostic workup of unrelated diseases were identified using the PACS radiology system. The CT thorax had been done with Siemens SOMATOM Emotion 16 of 16 slices (Siemens Aktiengesellschaft, Muenchen, Germany). Data were stored in Osirex. The CT thorax studies involving the full length of both the clavicles were selected. A 3-D reconstruction of the clavicle was done and images were reviewed in the bone window. Clavicles were oriented in axial, coronal, sagittal planes, and measurements were performed. Consecutive 32 patients were included in the study.

Inclusion Criteria

1. CT thorax involving the full length of clavicles of either gender above 18 years.

Exclusion Criteria

1. Congenital malformation of the clavicle.
2. Previous surgery of the clavicle.
3. Previous clavicle fracture.

The length of the clavicle (L) was obtained by joining the central points along the length of the clavicle between two articular surfaces (Fig. 1). The width of the clavicle in the axial plane was measured by constructing a line from a point on the anterior surface of the clavicle and extended to a point on the posterior surface. The distance between these two points was measured and defined as the width of the clavicle. The width at the sternal end (W_s), width at the acromial end (W_a), and the smallest width (W_{sm}) of the clavicle were measured (Fig. 2). The thickness of the clavicle in the coronal plane was measured by constructing a line from a point on the superior surface and extended to a point on the inferior surface. The distance between these two points was defined as the thickness of the clavicle in the coronal plane. The thickness at the sternal end (T_s) and the acromial end (T_a) were measured. The medial and lateral curvatures were fitted with circles most clearly suggesting an arc of curvature, their radii were measured and denoted as R_s for medial/sternal curvature and R_a for lateral/acromial curvature (Fig. 3). One line connecting the most posterior point of the medial end to the apex of the posterior edge of the lateral curvature and another line connecting the anterior point of the lateral end to the apex of the anterior edge of the medial curvature were drawn. The perpendicular distance from the apex of the posterior edge of medial curvature and the apex of the anterior edge of the lateral curvature to these lines was defined as the depth of curvature of medial/sternal curvature (D_s) and lateral/acromial curvature (D_a) respectively (Fig. 4). Measurements of the medullary canal

Fig. 1 True length of the clavicle measured from sternal end to the acromial end along the length of the clavicle

Fig. 2 In the axial plane width of the clavicle at the sternal end, acromial end and the smallest width of the clavicle was measured

Fig. 3 Radii of curvature measured by inscribing circles at medial and lateral curvature

Fig. 4 Depth of curvature

of the clavicle were done by dividing the clavicle into eight equal segments in the sagittal plane by 3D-parallel ranges from medial to lateral numbering from segment 1 (S1) to segment 8 (S8). Each segment was further sectioned at the midpoint and 2D image of that section of the clavicle was

projected. The height and width of the medullary canal in this section were measured and attributed to the respective segment. The segment containing the narrowest part of the medullary canal was noted (Fig. 5). The length of the medullary canal was measured from the sternal end of the

clavicle to the acromial end by dividing the clavicle in the axial plane and tracing the medullary canal along its length. Change in direction of the medullary canal was noted only for the lateral curvature because of its importance as cited earlier in the introduction (henceforth whenever the change of direction is considered it refers to the lateral curvature). This was done by dividing the clavicle in the axial plane. The distance from the sternal end to the change of direction was measured. The segment in which the change of direction of the medullary canal happens was noted (Fig. 6). Projection of the medullary canal to the lateral end of the clavicle from the narrowest part of the medullary canal was done and distance from the posterior part of the articular surface of the clavicle with the acromion to the projection was measured to know the hypothesized lateral entry portal (Fig. 7).

Fig. 5 Equal segments of the clavicle by 3D parallel ranges with its corresponding medullary canal

Fig. 6 Clavicle was divided in axial plane and the segment in which the change of direction of the medullary canal occurs was noted

Fig. 7 Projection of narrowest part of medullary canal to lateral end of the clavicle (lateral entry portal)

A perpendicular line from the medial edge of the coracoid process to the clavicle was drawn. The segment to which the coracoid process corresponds was noted and length from the lateral end of the clavicle to the perpendicular line was measured. The medial edge of the coracoid process defines the lateral end segment of the clavicle according to the AO group [14] (Fig. 8).

Statistical Analysis

Data were collected and tabulated in Microsoft excel sheet and later analyzed using SPSS software version 20. Mean and standard deviations were calculated. Unpaired t test was applied for comparison. $P < 0.05$ was considered as statistically significant.

Fig. 8 Lateral end segment of the clavicle measured from medial edge of the coracoid process to the lateral end of the clavicle

Results

Sixty-four clavicles of 32 patients (16 males, 16 females) were studied.

1. Length (L): The average length of the clavicle was 142.5 ± 12.2 mm (111.8–165 mm) in the studied population. The clavicles in males were significantly longer than of the females by 14.2 mm ($P=0.000$). The average length of the right clavicle was 141.5 ± 12.9 mm and of the left clavicle was 143.5 ± 11.5 mm.
2. Width: Male clavicles had more width at the middle of the clavicle (W_{sm}) than female and was found to be significant ($P=0.00$).
3. Thickness of the clavicle: The average thickness at the sternal end (T_s) was 23.3 ± 3.4 mm, while the average thickness at the acromial end (T_a) was 12.7 ± 2.2 mm (Table 1). Male clavicles were thicker at the sternal end than females and were found to be statistically significant ($P=0.00$). The average thickness at the acromial end of the clavicle for males and females was 12.9 ± 1.6 and 12.6 ± 2.8 mm respectively.
4. Radius of curvature: The average radius of medial curvature (R_s) was 49.3 ± 5.3 mm and lateral curvature (R_a) was 34 ± 4.4 mm (Table 1). The average radius of medial curvature for male and female clavicle was 51.3 ± 4.5 mm and 47.4 ± 5.4 mm respectively. The average radius of lateral curvature for male and female clavicle was 35.69 ± 3.9 mm and 32.69 ± 4.4 mm respectively. For both medial and lateral curvature, the average radius of curvature was more in males than females and was found to be statistically significant ($P=0.003$ and $P=0.006$) (Table 2).
5. Depth of curvature: The average depth of curvatures was larger in males than females at both ends and was found statistically significant at medial curvature but not at lateral curvature ($P=0.000$ and $P=0.3$) (Table 2).
6. Medullary canal of the clavicle: The average height and width of the narrowest part of the medullary canal of either gender were 2.4 ± 0.9 mm and 2.5 ± 1.0 mm (Table 1). In the elderly population (age ≥ 60 years) the average height and width of the narrowest part of the

medullary canal was 2.89 mm and 2.86 mm respectively. The narrowest part of the medullary canal was in segment 3 (S3) in 3 percent, segment 4 (S4) in 9.3%, segment 5 (S5) in 57.8 percent, segment 6 (S6) in 29.6% of the clavicle. The average length of the medullary canal was 136.7 ± 13.4 mm. The average length of medullary canals in male clavicles was significantly longer than that of the female clavicles by 14.5 mm ($P=0.000$).

7. Change of direction of the medullary canal: The average length from the sternal end of the clavicle to the change of direction of the medullary canal was 105.6 ± 9.6 mm. Seventy-five percent of clavicles had a change of direction in segment 6 (S6) and 25 percent of clavicles had a change of direction in segment 7 (S7).
8. Lateral entry portal: The average distance from the posterior part of the articular surface of the clavicle with the acromion to the projection line was 18.3 mm.
9. Coracoid process: The average length from the acromial end of the clavicle to the perpendicular line drawn from the medial edge of the coracoid process to the clavicle was 43 ± 7.0 mm (Table 1). Eighty-nine percent of clavicles had the medial edge of the coracoid process corresponding to segment 6 (S6) and 11 percent of clavicles to segment 7 (S7) in either gender.

Discussion

Clavicle shaft fractures have been managed commonly by conservative methods traditionally. Plating and intramedullary fixation are two commonly used surgical techniques for treating displaced clavicle shaft fractures. Morphometric data of the clavicle and its medullary canal will help design a better device and surgical technique. This study describes the morphometric features of the clavicle and its medullary canal in detail. We have measured the true length of the clavicle by the method mentioned earlier. Males had longer clavicles than females. The average length of the clavicle was 142.5 ± 12.2 mm. The length of the clavicles in the present study was less than the length of clavicles in the studies of Qiu et al. [13] (144.2 ± 12 mm, apparent length) in CT study, Andermahr

Table 1 Statistical analysis of parameters studied in mm

Parameters	<i>N</i>	Min	Max	Mean	SD
Age	64	18	85	50.19	18.30
Length (<i>L</i>)	64	111.80	165.0	142.568	12.21
Width at sternal end (<i>W_s</i>)	64	14.70	30.80	23.539	3.75
Width at acromial end (<i>W_a</i>)	64	11.00	25.90	20.725	3.02
Smallest width (<i>W_{sm}</i>)	64	8.70	14.70	11.540	1.44
Thickness at sternal end (<i>T_s</i>)	64	16.60	34.90	23.332	3.46
Thickness at acromial end (<i>T_a</i>)	64	5.90	18.40	12.771	2.29
Radius of curvature at sternal end (<i>R_s</i>)	64	39.50	68.00	49.381	5.36
Radius of curvature at acromial end (<i>R_a</i>)	64	27.00	46.60	34.192	4.45
Depth of curvature at sternal end (<i>D_s</i>)	64	10.70	25.10	17.748	2.90
Depth of curvature at acromial end (<i>D_a</i>)	64	5.80	18.60	11.137	2.92
S1H	64	6.60	24.60	14.706	3.63
S1W	64	7.00	20.80	13.839	3.11
S2H	64	2.50	12.70	6.789	2.17
S2W	64	1.90	14.50	6.689	2.43
S3H	64	1.00	10.10	4.623	1.76
S3W	64	1.00	10.60	4.443	2.01
S4H	64	1.00	6.30	3.214	1.15
S4W	64	1.00	7.30	3.192	1.29
S5H	64	1.10	5.20	2.776	1.06
S5W	64	1.00	5.00	2.865	1.15
S6H	64	1.20	7.70	3.248	1.58
S6W	64	1.20	8.50	3.178	1.64
S7H	64	1.10	10.10	4.623	2.53
S7W	64	1.40	13.10	5.154	2.41
S8H	64	2.40	21.20	8.239	4.34
S8W	64	1.30	23.30	12.41	5.79
Height of narrowest medullary canal (<i>H_n</i>)	64	1.00	5.100	2.456	0.99
Width of narrowest medullary canal (<i>W_n</i>)	64	1.00	5.000	2.520	1.06
Length of medullary canal (<i>LM</i>)	64	100.40	160.00	136.770	13.49
Point of change of direction of medullary canal	64	88.20	130.100	105.646	9.62
Projection to lateral end of clavicle	64	12.00	29.800	18.360	4.06
Lateral end segment of the clavicle	64	30.30	56.400	43.687	7.07

SD standard deviation, *S* segment, *H* height, *W* width

et al. [9] (151 ± 11 mm, apparent length) on cadaveric clavicles, King et al. [11] (151.15 mm, true length) in CT study (Table 3). Apparent length is the shortest distance between medial and the lateral end. Apparent length is shorter than true length for a given clavicle. The true length of the clavicles in this study was less than the apparent length of clavicles measured in other studies indicating clavicles are far shorter in this study. The average length of the clavicle in the Sushmita et al. [15] study was 124.3 mm and 124 mm for right and left clavicle respectively. Nagarchi et al. [16] study showed the average length of male and female clavicles was 142.90 mm and 132.30 mm respectively. These Indian morphometric studies were cadaveric based. Our clavicles were longer in either gender and side than these studies.

Compared to other studies we found that radii of both medial and lateral curvatures were smaller implying that clavicles in the present study are more curved. The average length of the medullary canal was 136.7 ± 13.4 mm. No earlier studies have measured the length of the medullary canal. We found the medullary canal extending up to the lateral end of the clavicle contrary to the belief that it is absent in the lateral end. In the present study, the narrowest part of the medullary canal corresponds to segment S5 in 57.8% and segment S6 in 29.6% of clavicles. This is beyond the midpoint of the clavicle in contradiction to earlier studies [11–13]. The average height and width of the narrowest part of the medullary canal were 2.4 ± 0.9 mm and 2.5 ± 1.0 mm, respectively. The narrowest medullary canal in King et al. [11] study was 4.05 mm in height and 5.2 mm in width,

Table 2 Comparison of clavicle morphometry between male and female in mm

Measurements	Male	Female	<i>P</i> value	95% CI for mean difference
Length (<i>L</i>)	149.67 ± 9.6	135.46 ± 10.3	0.000	9.22, 19.19
Width at sternal end (<i>W_s</i>)	24.05 ± 3.7	23.01 ± 3.7	0.271	−0.83, 2.91
Width at acromial end (<i>W_a</i>)	21.15 ± 3.3	20.29 ± 2.6	0.255	−0.64, 2.37
Smallest width (<i>W_{sm}</i>)	12.26 ± 1.2	10.81 ± 1.2	0.000	0.83, 2.08
Thickness at sternal end (<i>T_s</i>)	24.98 ± 3.0	21.68 ± 3.0	0.000	1.76, 4.82
Thickness at acromial end (<i>T_a</i>)	12.91 ± 1.6	12.62 ± 2.0	0.612	−0.85, 1.44
Radius of curvature at sternal end (<i>R_s</i>)	51.30 ± 4.5	47.46 ± 5.4	0.003	1.31, 6.35
Radius of curvature at acromial end (<i>R_a</i>)	35.69 ± 3.9	32.69 ± 4.4	0.006	0.89, 5.11
Depth of curvature at sternal end (<i>D_s</i>)	19.21 ± 2.3	16.27 ± 2.6	0.000	1.68, 4.19
Depth of curvature at acromial end (<i>D_a</i>)	11.49 ± 3.5	10.78 ± 2.0	0.335	−0.75, 2.17
Height of narrowest medullary canal (<i>H_n</i>)	2.62 ± 0.9	2.28 ± 1.0	0.171	−0.15, 0.83
Width of narrowest medullary canal (<i>W_n</i>)	2.73 ± 1.0	2.30 ± 1.0	0.115	−0.10, 0.94
Length of medullary canal (<i>LM</i>)	144.02 ± 10.7	129.51 ± 12.0	0.000	8.78, 20.22
Point of change of direction of medullary canal	109.86 ± 7.5	101.42 ± 9.7	0.000	4.08, 12.78
Projection to lateral end of clavicle	18.38 ± 4.0	18.33 ± 4.1	0.964	−1.99, 2.09
Lateral end segment of the clavicle	46.88 ± 6.0	40.49 ± 6.6	0.000	3.21, 9.56

Andermahr et al. [8] study was 6.7 ± 2.6 mm in diameter and Aira et al. [17] study was 3.82 ± 1.02 mm. We could not explain this gross difference in the medullary canal size. In 56 percent of clavicles narrowest size of the medullary canal was less than 2.4 mm in height and 2.5 mm in width. This suggests that in more than half of the clavicle shaft fractures it may be difficult to insert an intramedullary nail of size 2.5 mm or more without reaming or enlarging the medullary canal. This may necessitate an open technique and in some instances, nailing may have to be abandoned to adopt an alternative fixation method. Intramedullary fixation of clavicle shaft fractures are commonly done with titanium elastic nails and modified Hagie pins. The entry portal for titanium elastic nails is at the medial end of the clavicle and for modified Hagie pins is at the lateral end of the clavicle medial to acromioclavicular joint posteriorly. The intramedullary device is introduced and advanced across the fracture site by closed or open technique. Fractures of the lateral half of the clavicle involving segment S5 and segment S6 may be difficult to nail from the medial side as the medullary canal is narrow and changes its direction. We hypothesize that the lateral entry portal as suggested by us may work better for these fractures as it is in more straight alignment with the medullary canal. This may be an appropriate entry point for the intramedullary devices introduced from the lateral end of the clavicle. In 89 percent of the clavicles medial edge of the coracoid process corresponded to segment S6. The change of direction of the medullary canal also happened to be from the S6 segment in 75 percent of the clavicles. So, the coracoid process may mark the change of direction of the medullary canal and also the beginning of the lateral

end segment of the clavicle as referred to by the AO group [14]. The coracoid process is a reliable anatomical landmark corresponding to the narrow part of the medullary canal and change of direction of the medullary canal, which can be easily recognized even on a plain radiograph. Fractures at the coracoid process or just medial to it may require to be nailed from the lateral entry portal. Limitations of this study are, it has a small sample size and represents a small geographic population. The position of the clavicle in the CT scans was not in the anatomical position when studied.

Conclusion

This study provides the morphometric features of the clavicle and its medullary canal of the studied population. The clavicles are shorter and more curved than other studies. The average dimension of the medullary canal at the narrowest part is less than 2.5 mm in more than half of the clavicles. This may necessitate reaming to enlarge the medullary canal to engage an adequate size intramedullary device or may require open technique. The narrowest part of the medullary canal is at segment S5. Change of direction of the medullary canal happens at segment S6 and also corresponds to the medial edge of the coracoid process consistently. The direction of the medullary canal at segment S5 and S6 is more aligned to our hypothesized lateral entry portal at the lateral end of the clavicle. Hence, fractures at segments S5 and S6 may be easily nailed from the lateral end. The coracoid process is a reliable anatomical landmark to recognize these fractures.

Table 3 Comparison of the clavicle morphology with other studies in mm

Measurements	Groups	Present study India	Qui et al. [13] China	Mathieu et al. [12] France	Andermahr et al. [9] Germany	King et al. [11] South Africa
		CT based True length	CT based Apparent length	CT based Apparent length	Cadaveric Apparent length	CT based True length
Length (L)	Total	142.5 ± 12.2	144.2 ± 12		151 ± 11	151.15
	Male	149.6 ± 9.6	152.9 ± 9.3	152.7 ± 2.9	156 ± 10	156.8 ± 9.7
	Female	135.4 ± 10.3	135.6 ± 7.2	140.2 ± 1.5	146 ± 10	145.7 ± 7.9
Width at sternal end (W_s)	Total	23.5 ± 3.7	22.1 ± 3.6		25.5 ± 4	
	Male	24 ± 3.7	24.1 ± 3.2	24.3 ± 0.9	26 ± 4	14.55 ± 2.25
	Female	23.0 ± 3.7	20.2 ± 2.8	21.4 ± 2.1	24 ± 4	12.27 ± 1.85
Width at the acromial end (W_a)	Total	20.7 ± 3.02	22.7 ± 4.1		22 ± 4	
	Male	21.1 ± 3.3	25.1 ± 3.6	22.5 ± 0.8	24 ± 4	18.26 ± 3.04
	Female	20.2 ± 2.6	20.3 ± 2.9	19.4 ± 1.3	21 ± 4	15.14 ± 2.53
Smallest width (W_{sm})	Total	11.5 ± 1.4	11.4 ± 2.1		12 ± 2	
	Male	12.2 ± 1.2	12.7 ± 1.7		13 ± 2	12.71 ± 1.71
	Female	10.8 ± 1.2	10.2 ± 1.3		11 ± 1	11.08 ± 1.14
Thickness at the sternal end (T_s)	Total	23.3 ± 3.4	20.8 ± 6.0			
	Male	24.9 ± 3.0	21.1 ± 7.5			14.55 ± 2.77
	Female	21.6 ± 3.0	20.6 ± 4.1			13.57 ± 2.25
Thickness at the acromial end (T_a)	Total	12.7 ± 2.2	14.1 ± 3.8			
	Male	12.91 ± 1.6	16.3 ± 3.8			10.56 ± 1.96
	Female	12.6 ± 2.8	11.9 ± 2.2			9.74 ± 1.65
Radius of curvature at the sternal end (R_s)	Total	49.3 ± 5.3	63.2 ± 12.1		71 ± 13	
	Male	51 ± 4.5	66.4 ± 12.8	72.1 ± 1.4	73 ± 13	
	Female	47 ± 5.4	60.0 ± 10.6	68.7 ± 1.2	70 ± 12	
Radius of curvature at the acromial end (R_a)	Total	34.1 ± 4.4	29.4 ± 8.2		39 ± 14	
	Male	35.6 ± 3.9	28.8 ± 8.2	37.1 ± 1.2	36 ± 11	
	Female	32.6 ± 4.4	30.1 ± 8.1	37.8 ± 0.9	42 ± 16	
Depth of curvature at the sternal end (D_s)	Total	17.7 ± 2.9	17.4 ± 4.0		17 ± 3	
	Male	19.2 ± 2.3	19.7 ± 3.0	18.4 ± 1.6	17 ± 3	
	Female	16.2 ± 2.6	15.2 ± 3.6	15.1 ± 1	16 ± 4	
Depth of curvature at the acromial end (D_a)	Total	11.1 ± 2.9	12.7 ± 3.3		12 ± 3	
	Male	11.4 ± 3.5	14.0 ± 3.5	12.3 ± 1.5	13 ± 3	
	Female	10.7 ± 2.0	11.3 ± 2.5	10.2 ± 0.6	11 ± 3	
Length of medullary canal	Total	136.7 ± 13.4				
	Male	144.0 ± 10.7				
	Female	129.5 ± 12.0				

Informed consent For this type of study informed consent is not required.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical standard statement This article does not contain any studies with human or animal subjects performed by the any of the authors.

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