ACTA MORPHOLOGICA
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Member of the European Federation of Experimental Morphology (EFEM)
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ORIGINAL ARTICLE

RELATION OF RENAL ULTRASONOGRAPHIC MEASUREMENTS WITH BODY HEIGHT

University Clinic of Nephrology, Skopje, Republic of North Macedonia

ABSTRACT

Introduction: Kidney size has been found to be correlated with anthropometric features and is different among different ethnicities. In this study, we used ultrasonography for measurement of kidney volumes in healthy individuals and evaluated the relationships with body height, age and gender.

Materials and methods: We conducted a cross-sectional observational study and evaluated 108 healthy individuals whose serum creatinine level was within reference range. Patients’ medical clinical and laboratory records were reviewed. Age, gender and height were recorded. Pearson correlation coefficients were used to evaluate the strength of association between ultrasonographic parameters with each other and with other parameters, and were expressed as r². Variations in left and right renal dimensions between various age groups were compared using a one-way analysis of variance, followed by a post-hoc Tukey’s test.

Results: Subjects’ age ranged from 16 to 84 years and the mean age was over 50 years. There was an equal distribution among genders. Strong and positive correlations were seen for the measured length, parenchyma thickness and also for both total and parenchymal volumes with subjects’ height for both kidneys. The strongest correlations were observed for the left and right kidney length and also for the right kidney parenchymal volume (r=0.536, p=0.001; r=0.469, p=0.001; r=0.44, p=0.001). On the opposite, most of the relations with age were negative, but week and insignificant. When we divided the study subjects into three age groups and compared them for the height, there was no significant difference among them. Regarding the parenchymal and total kidney volumes of both kidneys, the different age groups showed similar findings in the ultrasonographic measurements. The mean calculated volumes were slightly declining with age and showed the largest values in the first group of patients under 30 years and lowest values in patients over 70 years old. Ultrasonographic measurements were also compared among the two genders. Both (men and women) showed similar age (53.55 ± 18.22 vs. 50.79 ± 18.13 p= 0.430, respectively). As for the height, men were significantly taller than women (1.734 ± 0.007 vs. 1.637 ± 0.005, p= 0.001). The kidney length, volume and parenchymal volumes of both kidneys were significantly larger in men.

Conclusion: Renal length and volume are strongly correlated with body height. This relation must be considered in clinical decisions on further investigations regarding kidney disease progression.

INTRODUCTION

In spite of the significant improvement in the prevention and treatment of kidney diseases, there is continuous increase in the number of patient deaths caused by chronic kidney disease. More than 80% of all patients who receive treatment for kidney failure are in affluent countries with universal access to health care and large number of elderly populations [1]. Ultrasound investigation is a useful, an accessible, inexpensive and fast aid for decision-making in patients with renal symptoms and for guidance in renal intervention [2].
Many published studies reported kidney dimensions in healthy persons and CKD population [3-6]. Kidney measurements as length, width and parenchymal thickness are used most frequently in clinical practice. Also, total kidney volume and parenchymal volume are considered important parameters in kidney morphology. However, renal ultrasound has certain limitations, and other modalities, such as CT and MRI, are at disposal as supplementary imaging modalities in the assessment of renal disease [2]. Kidney size has been found to be correlated with anthropometric features and kidney function. The renal length correlates with body height and renal volume and the renal volume is larger in males than in females [3,8]. The renal function is known to decrease progressively with age even in healthy individuals, in a process called nephrosenescence [9 – 11]. The age-related loss of cortical volume from nephrosclerosis is masked to some extent, by the age-related tubular hypertrophy. Detection of this mild but progressive nephrosclerosis with aging is difficult without a kidney biopsy. Nonetheless, nephrosclerosis leads to macrostructural findings on imaging studies, including a decrease in cortical volume [12]. Kidney size for similar weight and height is different among different ethnicities. Several studies reported differences in nomograms in respect of ethnic race [13-16]. In this study, we used ultrasonography for measurement of kidney volumes in healthy individuals and evaluated the relationships with body height, age and gender.

**MATERIAL AND METHODS**

We conducted a cross-sectional observational study and evaluated 108 healthy individuals whose serum creatinine level was within reference range (23 health care workers, 8 young doctors - trainees, 2 potential kidney donors and 75 outpatients evaluated for common clinical complaints such as abdominal pain or prostatic hyperplasia). Patients’ medical clinical and laboratory records were reviewed. Age, gender and height were recorded. Subjects with underlying disease such as hypertension, diabetes mellitus and heart disease or any abnormal finding at ultrasonographic examination (renal cysts, hydronephrosis, single kidney, kidney stone and mass, increased parenchymal echogenicity, extreme obesity or pregnancy, or abnormal laboratory findings) were excluded. Three nephrologists performed ultrasonography in all subjects in supine position using the same ultrasound device with 3.5 MHz convex transducer. The pole to pole length, width, total thickness and parenchymal thickness were measured in both kidneys. Kidney volume was calculated by the formula: length x thickness x width x 0.523 (17). Parenchymal volume was calculated as total volume - sinus volume. For clarification of a potential decline in kidney volume with age, the study participants were divided empirically into three age groups: <30 yr, 31 to 70 yr, and >70 yr. Finer gradations (e.g., by decade) were not made because of the relatively small number of subjects within each gender. Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) 23.0 software package (Version 23, SPSS Inc., Chicago, IL, USA). Parameters were expressed as mean ± SD. Student’s t-test was used to compare continuous variables. Pearson correlation coefficients were used to evaluate the strength of association between ultrasonographic parameters with each other and with other parameters, and were expressed as \( r^2 \). Variations in left and right renal dimensions between various age groups were compared using a one-way analysis of variance, followed by a post-hoc Tukey's test. Statistical significance was set at \( p<0.05 \).

**RESULTS**

A total of 108 individuals were evaluated by ultrasonography. The demographic characteristics and kidney measurements are shown in Table 1. Subjects’ age ranged from 16 to 84 years and the mean age was over 50 years. There was an equal distribution among genders. The mean body height was 168 cm. The mean length of the right kidney was 108.57, the width 47.5 and the thickness of the parenchyma 1.74 cm.
The calculated mean total volume exceeded 130 cm$^3$ and parenchymal volume was around 120 cm$^3$. All mean measurements of the left kidney showed slightly longer values (mean length 110.25 cm, width 51.02 cm, thickness 1.78 cm). The mean calculations also showed that the left total and parenchymal kidney volumes were larger than those of the right one (153.75 cm$^3$, 141.54 cm$^3$).

### Table 1. Study group characteristics

<table>
<thead>
<tr>
<th>N= 108</th>
<th>Mean ± SD</th>
<th>range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>52.17 ± 18.04</td>
<td>18 - 84</td>
</tr>
<tr>
<td>Gender</td>
<td>54 (50%)</td>
<td></td>
</tr>
<tr>
<td>Height (cm)</td>
<td>168 ± 7.7</td>
<td>151 – 190</td>
</tr>
<tr>
<td>Right kidney length (cm)</td>
<td>108.57 ± 7.27</td>
<td>83 - 126</td>
</tr>
<tr>
<td>Width (cm)</td>
<td>47.5 ± 6.88</td>
<td>34 – 65</td>
</tr>
<tr>
<td>Thickness (cm)</td>
<td>1.74 ± 0.19</td>
<td>1.4 – 2.2</td>
</tr>
<tr>
<td>Total Volume (cm$^3$)</td>
<td>131.82 ± 43.51</td>
<td>53.18 – 269.58</td>
</tr>
<tr>
<td>Parenchymal Volume (cm$^3$)</td>
<td>121.94 ± 39.58</td>
<td>51.58 – 252.45</td>
</tr>
<tr>
<td>Left kidney length (cm)</td>
<td>110.25 ± 7.17</td>
<td>92 – 128</td>
</tr>
<tr>
<td>Width (cm)</td>
<td>51.02 ± 6.84</td>
<td>31 – 66</td>
</tr>
<tr>
<td>Thickness (cm)</td>
<td>1.78 ± 0.18</td>
<td>1.4 – 2.4</td>
</tr>
<tr>
<td>Total Volume (cm$^3$)</td>
<td>153.76 ± 44.42</td>
<td>47.24 – 287.05</td>
</tr>
<tr>
<td>Parenchymal Volume (cm$^3$)</td>
<td>141.54 ± 40.17</td>
<td>46.58 – 272.37</td>
</tr>
</tbody>
</table>

The relations between sonography measurements, age and height are shown in Table 2. Strong and positive correlations were found for the measured length, parenchymal thickness and also for both total and parenchymal volumes with subjects’ height for both kidneys. The strongest correlations were observed for the left and right kidney length and also for the right kidney parenchymal volume ($r$=0.536, p=0.001; $r$=0.469, p=0.001; $r$=0.441, p=0.001). On the opposite, most of the relations with the age were negative, but week and insignificant.

### Table 2. Correlations between sonography measurements with age and height

<table>
<thead>
<tr>
<th>MKL</th>
<th>MKP</th>
<th>MTV</th>
<th>MKPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>R</td>
<td>L</td>
<td>R</td>
<td>L</td>
</tr>
<tr>
<td>Hei ght (m)</td>
<td>0.46 9**</td>
<td>0.53 6**</td>
<td>0.26 0*</td>
</tr>
<tr>
<td>Age (years)</td>
<td>0.094*</td>
<td>0.010*</td>
<td>0.174*</td>
</tr>
</tbody>
</table>

**p<0.001; * p<0.01; * p>0.05; MKL = Mean kidney length; MKP= Mean kidney parenchymal thickness; MTV = Mean total volume; MPV = Mean kidney parenchymal volume; R = right; L = left

The right kidney total and parenchymal volumes were plotted against height (Figure 1). A positive trend of kidney enlargement with the increment of subjects’ height was observed. The same finding was also seen for the parenchymal and total volume of the left kidney. (Figure 2).
Fig 1. Total and parenchymal volumes of the right kidney in correlation to height

Fig 2. Total and parenchymal volumes of the left kidney in correlation to height
When we divided the study subjects into three age groups and compared them for the height, there was no significant difference among them (Table 3). There were 30 subjects with age under 30 years, 21 subject of age over 70 years and most of the subjects (57) were between 31 and 70 years old. The three groups did not differ in respect of height.

Regarding the parenchymal and total kidney volumes of both kidneys, the different age groups showed similar findings in the ultrasonographic measurements. The mean calculated volumes were slightly declining with age and showed the largest values in the first group of patients under 30 years and lowest values in patients over 70 years old (/Figure 3), but the difference was not significant.

Table 3. Age groups characteristics in respect to height, total and parenchymal volume

<table>
<thead>
<tr>
<th>Age groups (years)</th>
<th>Height (cm)</th>
<th>RKPV ((\text{cm}^3))</th>
<th>LKPV ((\text{cm}^3))</th>
<th>RKTV ((\text{cm}^3))</th>
<th>LKTV ((\text{cm}^3))</th>
</tr>
</thead>
<tbody>
<tr>
<td>18–30 [N=30]</td>
<td>170 ± 6.4</td>
<td>127.53±44.13</td>
<td>139.06±47.43</td>
<td>137.27±48.94</td>
<td>150.34±52.42</td>
</tr>
<tr>
<td>31–70 [N=57]</td>
<td>168 ± 7.9</td>
<td>120.94 ± 39.76</td>
<td>145.68±37.94</td>
<td>130.52±43.62</td>
<td>158.00±41.82</td>
</tr>
<tr>
<td>&gt;70 [N=21]</td>
<td>168 ± 6.3</td>
<td>116.64±32.37</td>
<td>133.86±34.95</td>
<td>127.54±35.46</td>
<td>145.82±39.10</td>
</tr>
</tbody>
</table>

RKPV— right kidney parenchymal volume; LKPV- left kidney parenchymal volume; LKPV-left kidney parenchymal volume; RKTV– right kidney total volume; LKTV- left kidney total volume

Fig 3. Mean total and parenchymal volume of kidneys in different age groups

Ultrasonographic measurements were also compared among the two genders (Table 4). Both genders (men and women) showed similar age (53.55 ± 18.22 vs. 50.79 ± 18.13 p= 0.430, respectively). As for the height, men were significantly taller than women (1.734 ± 0.007 vs. 1.637 ± 0.005, p= 0.001). The kidney length, volume and parenchymal volumes of both kidneys were significantly larger in men.
Table 4. Kidney measurements according to gender

<table>
<thead>
<tr>
<th></th>
<th>WOMEN</th>
<th>MÉN</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Right</td>
<td>Left</td>
</tr>
<tr>
<td>KL (cm)</td>
<td>106.35 ± 6.62</td>
<td>107.90 ± 7.25</td>
<td>110.79 ± 6.97</td>
</tr>
<tr>
<td>TKV (cm³)</td>
<td>117.64 ± 28.33</td>
<td>138.30 ± 32.79</td>
<td>146.00 ± 51.24</td>
</tr>
<tr>
<td>TPV (cm³)</td>
<td>109.10 ± 24.98</td>
<td>127.74 ± 29.19</td>
<td>134.77 ± 46.92</td>
</tr>
</tbody>
</table>

KL - Kidney length; TKV - Total kidney volume; TPV - Total parenchymal volume

DISCUSSION

Kidney volume was found to be the best indicator of renal size [3,15,18,19]. But, recent studies have emphasized the correction of the renal sonographic parameters for body height, which also strengthens the degree of correlation with GFR [7,19]. Anthropologic population characteristics seem to play a crucial part in ethnic differences among subjects considering renal measurements [4,13,20], indicating the need of developing standard nomograms. In our study we investigated 108 subjects of different age and gender. All measurements were quite close to findings presented in western population studies, such as from Denmark [20], but quite different than results in eastern populations studies [14,16]. The mean kidney length, volume and as well as parenchymal volume of the left kidney were significantly larger than those of the right kidney. Those findings were similar to Musas [8] and Ezes [13] studies, but opposite to Emamians [3]. Since we measured the length of the kidneys only in supine position, one cannot exclude the possibility of interference of the ultrasound depth difference on both sides. The measurements were performed by three nephrologists and all of them got the same results measuring the left kidney larger. As for the gender, all measurements were larger in men than in women, as it was published in many other studies that corrected for body height [2,7,21]. Also, in our study, men were taller than women. A strong and positive correlation was observed for kidney parameters with height and these relations were also conformed in many other studies [3,13,15]. Some investigators, like Aroojs [20], found the volume to be best correlated with height, but others found it were the kidney width and body weight [16] that correlated best. In our study, the kidney length had the strongest relation to height. In respect of age, we failed to show a significant declination of kidney proportions with ageing. Still, the mean values showed a slight fall from younger to elderly. The small number of participants limited our study in confirmation of that finding [15, 22]. But also, there is the possible explanation of remaining similar parenchymal thickness with ageing by enlargement of the medulla on behalf of the diminishing glomeruli [3,12]. Another limitation of our study was the lack of the data on the subjects’ body weight. This parameter is also influential on kidney size [16], particularly having in mind the intercultural differences and nutritional habits. Still, with this study we documented the findings on our healthy population kidney measurements, which are important for CKD screening and monitoring kidney function.
CONCLUSION
Renal ultrasonography measurements are methods of choice in current clinical practice. Renal length and volume are strongly correlated with body height. This relation must be considered in clinical decisions on further investigations regarding kidney disease progression.

REFERENCES


ORIGINAL ARTICLE

SURGICAL TREATMENT OF AC DISLOCATION GRADE III OR IV WITH THIGHT ROPE SYSTEM: A RETROSPECTIVE STUDY AT THE CLINIC OF TRAUMATOLOGY - SKOPJE IN THE PERIOD 2015 – 2018

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¹University Clinic of Traumatology (TOARILUC), Skopje, Republic of North Macedonia
²University Clinic of Neurosurgery, Skopje, Republic of North Macedonia
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ABSTRACT

Introduction: Acromioclavicular (AC) dislocation is a common injury with incidence of 3 to 4 per 100 000 in the general population. It is more common in younger, athletic patients. In 1984, Rockwood modified Tossy et al. and Allman classification by including types IV, V, and VI and we used that classification in our study. The aim of our study was to evaluate the surgical treatment of AC dislocation grade III or IV with TightRope system from a functional aspect.

Materials and methods: In the period between 2015 and 2018, 32 patients with type III (14 patients) or IV AC dislocation (18 patients) with female to male ratio 0.45 (f:m=10:22) were treated at the Clinic of Traumatology, Skopje. Inclusion criteria were applied to all patients. Three radiographic views were used: AP view, true axillary view and stress view of both sides of the AC joint and CC ligament. All patients were surgically treated with tight rope technique.

Results: DASH (Disabilities of the Arm, Shoulder and Hand) and VAS (Visual Analogue Scale) scores were used for functional evaluation preoperatively and postoperatively. The DASH questionnaire was used as an indicator of the impact of impairment on the level and type of disability.

Discussion: The advantages of the TightRope system are permanent fixation and normal physiologic movement of the joint. Complications include loss of reduction, subsidence and displacement of the endobuttons and posterior displacement of the clavicle.

Conclusion: The technique proved to be effective in treating acute AC dislocations (Rockwood type III or IV) with a high degree of excellent and good functional results.

Keywords: diastasis, ThightRope, functional scores.

INTRODUCTION

Acromioclavicular (AC) dislocation is a common injury. Overall incidence is 3 to 4 per 100 000 in the general population, with 25% to 52% occurring during sport activities. It does not include typical age range, but it is more common in younger, athletic patients. AC joint dislocation is often diagnosed after road traffic accidents, a fall on the side of the body and direct blow to the lateral aspect of the shoulder with the arm in an adducted position. The mechanism most commonly involved in AC and CC ligament injuries is a direct force applied on the superior surface of the acromion; it is usually the consequence of a fall with the arm in an adducted position.
Less frequently, an indirect force may be transmitted to the shoulder because of a fall on an outstretched hand or elbow. The AC capsular ligaments provide most of the joint stability in the anteroposterior direction. The coracoacromial ligament provides most of the joint stability in the anteroposterior direction. The coracoclavicular (CC) ligaments, on the contrary, provide vertical stability. Tossy et al. and Allman initially described the classification of acromioclavicular injuries as types I, II, and III in the 1960s. In 1984, Rockwood modified this classification to include types IV, V, and VI and we used that classification in this study. Treatment of grade I and II AC joint dislocations can be performed conservatively. However, surgical intervention is required for patients with grades III (especially individuals who are workers with heavy manual occupations, overhead throwing athletes, and so on) and IV–VI (because of their common characteristics including instability in the horizontal and vertical direction due to AC ligament and coracoclavicular (CC) ligament disruption). There is still a lack of consensus on whether to conserve or operate type III AC joint dislocations. The surgical treatment varies between mechanical fixation or synthetic materials or biologic anatomic reconstructions.

The aim of our study was to evaluate surgical treatment of AC dislocation grade III or IV with TightRope system from a functional aspect.

**MATERIALS AND METHODS**

In the period between 2015 and 2018 32 patients with type III (14 patients) or IV AC dislocation (18 patients), with female to male ratio 0.45 (f:m=10:22) were treated at the Clinic of Traumatology, Skopje. All patients were younger than 55 years (range 18 to 54 years) and were physically active. All patients were operated within 48 hours after trauma event. Inclusion criteria were: 1) All cases of acute AC joint and type III or IV dislocation according to the Rockwood classification, 2) No history of shoulder injuries and related operations, 3) Follow-up time more than 10 months. 4) Type III cases were enrolled into the study if the distal end of the clavicle was located more or equal to 75 to 100% of its articular surface width in the radiographs and if painful palpation and protuberance shape of the clavicle during shoulder anterior raising in clinical diagnosis existed 4) Isolated injury. Conditions against surgery were considered: elderly, obese, sedentary patients, non-manual laborer, non-dominant side, reducible joint, little apparent deformity and polytraumatised patients.

In order to determine the injury type, three radiographic views were used: AP view (with 10 degrees cranial tilt of the beam or Zanca view), true axillary view in the supine position and stress view of both sides of the AC joint and CC ligament. Anteroposterior, lateral, and axial views are standard views taken for the shoulder. Weighted X-rays can help differentiate type I from type II injuries and more importantly type II from occult type III injuries.

The stability of the shoulder and AC joint reduction was evaluated when the patient was placed in the beach chair position. All examinations were performed under local or general anesthesia. For controlling the infection, three doses of cephalosporin (second-generation) were administered to all patients. At first, the injured upper limb of the subject was prepped and draped in the normal sterile condition. For this purpose, the anatomical landmarks such as anterior portion of the acromion, distal clavicle, and coracoid process were used to determine the skin incision. A 4-6 cm skin incision was made after palpation of the coracoid process tip, and from the distance between the base of the coracoid process and 2.5 cm posterior to the AC joint was opened. Then the incision line was expanded on the subcutaneous tissue. Next, 2.5 cm to the AC joint the anterior deltoid muscle was split to ease the exposure of the coracoid process base.

Then the distance between coracoid process and distal part of the clavicle was split. The tissue was dissected medially and laterally by a curved soft tissue elevator.
Surgical treatment of AC dislocation grade III or IV with tight rope system: a retrospective study at the Clinic of Traumatology - Skopje in the period 2015 – 2018

Lateral flap was continued to expose the AC joint. In the first step, a 2.4 mm guide pin was placed in the central point of the base of the coracoid process. Then, the guide pin was carefully overdrilled by a 4.5 mm drill.

In the next step, the center of the distance between the anterior and posterior borders from the superior surface of the clavicle was drilled in the same condition and then the guide pin and drill were removed. At first, the Tight Rope device was inserted into the hole on the clavicle and then through the coracoid hole by a button inserter. Then, the first button was flipped and fixed under the base of the coracoid process by pulling one of the traction sutures (Fig.1).

![Fig1.](image)

**Fig1.** M, 32 Y, a construction worker, fall on the shoulder while cycling, AC dislocation grade III. DASH score 0; VAS score 2

In this step, AC joint reduction was performed in the anatomical position under pressure using the fluoroscopic visualization. In this position, the second button was placed and fixed on the superior surface of the clavicle and finally, while an assistant held the reduction, the button was secured by about five knots. According to post-operative protocol, shoulder mobilization was put.

**RESULTS**

DASH (Disabilities of the Arm, Shoulder and Hand) and VAS (Visual Analogue Scale) scores were evaluated preoperatively and postoperatively. The Disabilities of the Arm, Shoulder and Hand (DASH) outcome measure is a 30-item, self-report questionnaire designed to assess the patient’s health status during the previous week. The items enquire about the degree of difficulty in performing different physical activities because of arm, shoulder and hand problems (21 items), the severity of each of the symptoms of pain, activity-related pain, tingling, weakness and stiffness (five items) and the impact of the problem on social functioning, work, sleep and self-image (four items). Each item has five response options (no difficulty, mild difficulty, moderate difficulty, severe difficulty, unable). The scores are then used to calculate a scale score ranging from 0 (no disability) to 100 (most severe disability).

The DASH questionnaire is used as an indicator of the impact of impairment on the level and type of disability. The results obtained in this study were in favor of excellent functionality of the operated shoulder (Table 1. and Table 2).
Table 1. Results of DASH (Disabilities of the Arm, Shoulder and Hand) evaluation 3 months after surgery

<table>
<thead>
<tr>
<th>DASH SCORING</th>
<th>AC dislocation type III</th>
<th>AC dislocation type IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>No difficulty</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Mild difficulty</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Moderate difficulty</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Severe difficulty</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Unable</td>
<td>/</td>
<td>/</td>
</tr>
</tbody>
</table>

Table 2. Results of DASH (Disabilities of the Arm, Shoulder and Hand) evaluation 1 year after surgery

<table>
<thead>
<tr>
<th>DASH SCORING</th>
<th>AC dislocation type III</th>
<th>AC dislocation type IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>No difficulty</td>
<td>13</td>
<td>15</td>
</tr>
<tr>
<td>Mild difficulty</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Moderate difficulty</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Severe difficulty</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Unable</td>
<td>/</td>
<td>/</td>
</tr>
</tbody>
</table>

There was no significant difference between functional result at the third month and one year after surgery (p<0.5). VAS pain scale consists of four categories - no pain (0–4), mild pain (5–44), moderate pain (45–74), and severe pain (75–100). Majority of the patients had no greater pain (Table 3 and Table 4).

Table 3. VAS (Visual Analogue Scale) 3 months after surgery

<table>
<thead>
<tr>
<th>VAS SCORING</th>
<th>AC dislocation type III</th>
<th>AC dislocation type IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pain</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>Mild pain</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Moderate pain</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Severe pain</td>
<td>/</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 4. VAS (Visual Analogue Scale) 1 year after surgery

<table>
<thead>
<tr>
<th>VAS SCORING</th>
<th>AC dislocation type III</th>
<th>AC dislocation type IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pain</td>
<td>14</td>
<td>13</td>
</tr>
<tr>
<td>Mild pain</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Moderate pain</td>
<td>/</td>
<td>1</td>
</tr>
<tr>
<td>Severe pain</td>
<td>/</td>
<td>/</td>
</tr>
</tbody>
</table>

DISCUSSION

One advantage of the TightRope system is that it is a permanent device and thus does not need a separate operation to remove fixation hardware [1,2]. Another advantage is that it maintains reduction, yet allows for normal physiologic movement at the joint. Complications include loss of reduction (which could in part be due to the suture abrasion from other fixation hardware against sharp bony fragments), subsidence and displacement of the endobuttons (thought to be due to the use of a larger drill bit to create the portal), and posterior displacement of the clavicle with respect to the anterior edge of the acromion, which is best evaluated on axillary views [3,4].
The relationship of the two endobuttons to each other is fixed by the suture that holds them together, and it is important to pay attention to the space between the endobuttons on subsequent follow-up films [3,5,6]. If this space increases, it suggests that the suture has broken or become undone. On the plus side, the endobutton is much easier surgical option for the patients because there is no need to remove it [7].

CONCLUSION
The technique proved to be effective in treating acute AC dislocations (Rockwood type III or IV) with a high degree of excellent and good functional results.

REFERENCES
ORIGINAL ARTICLE

MUSCLE THICKNESS, PENNATION ANGLE AND ECHO-INTENSITY OF RECTUS FEMORIS AND GASTROCNEMIUS MEDIALIS MUSCLE MEASURED BY ULTRASOUND AS BIOMARKERS FOR SARCOPENIA

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ABSTRACT
Introduction: Sarcopenia is the progressive loss of muscle mass and function, leading to invalidity, decreased life quality, and death.
Objectives: To see whether ultrasound muscle parameters can be used to diagnose sarcopenia, compared to CT clinical tests.
Materials and methods: 169 participants, age 20 or above were included. The CSA at L3 vertebral body level was measured. The handgrip strength was established using a hand dynamometer, and muscle performance was measured with a gait speed test. Muscle thickness, echo intensity, and pennation angle of the rectus femoris and the gastrocnemius medialis muscles were measured sonographically.
Results: 32 patients were diagnosed as sarcopenic. There is a positive correlation between muscle thickness of the rectus femoris muscle and abdominal CSA (p<0.05). Correlation between pennation angle, echo intensity, and gait speed (p<0.05), and between pennation angle, echo intensity, and handgrip strength for both muscles exist (p<0.05).
Conclusion: ultrasound is a precise method for diagnosing muscle mass and function loss in sarcopenia.
Keywords: sarcopenia, ultrasound, muscle strength and performance.

INTRODUCTION
The term “sarcopenia” was originally described by Irwin Rosenberg in 1989. Rosenberg defined the disease as a reduction of muscle mass associated with aging [1]. Researches in following years confirmed the role of muscle mass reduction in the development of sarcopenia, but also added the reduction of muscle function and muscle strength as at least equal components in the initiation and progress of the syndrome. Even if the muscle mass remains constant, muscle strength and function reduce with ageing [2, 3]. Muscle power reduction is even greater than the muscle strength loss.
An increased interest in these topics and an increased number of studies related to sarcopenia altered and updated the meaning of the term “sarcopenia.” Today, the definition for sarcopenia accepted as the most adequate and most complete is the one developed in 2010 by the European Working Group on Sarcopenia in Older People (EWGSOP). The group defined sarcopenia as a syndrome of generalised and progressive reduction of muscle mass and muscle strength, which increases the risk for adverse outcome, such as invalidity, life quality decrease, and death. The group stressed reduction of physical performance and/or muscle strength in combination with muscle mass in order to establish the diagnosis of sarcopenia [4].
Sarcopenia can be primary, appearing as a part of the aging process. A secondary sarcopenic loss of muscle mass and function is related to various pathological processes and conditions, which are not directly associated with the aging process and can affect younger people. Conditions include but are not limited to inflammatory processes, neuromuscular disorders, hormonal disorders, primarily diabetes mellitus, malignancy, and other chronic conditions [4, 5].

Prevalence of sarcopenia increases with age. Muscle fibres atrophy appears relatively early, after the age of 30. However, the muscle atrophy is not linear and increases rapidly after the age of 65 [6]. Five to 13% of the population between age of 60 and 70 have sarcopenia, and the percentage in the elderly is even bigger and gets up to 50% at the age of 80 or above [7,8]. It is estimated that about 50 million people have sarcopenia at this particular moment, but with the expected aging of the world population, as many as 200 million people might face the syndrome 40 years from now [9].

A number of recent studies give detailed description of the relationship between the cross sectional area (CSA) of the psoas muscle, the paravertebral muscle CSA, or the summed CSA of the muscles at a particular axial cross sectional level of the human body, measured with Computed Tomography (CT) of the thorax or the abdomen and the total skeletal muscle mass. In addition, cut-off values for reduced muscle mass in sarcopenia developed from CT exams of the thorax or the abdomen have appeared in the past few years [10, 11].

Muscle mass and function reduction in sarcopenia is not linear throughout the body, and is most prominent in the gravity/antigravity muscles [12]. The majority of these muscles have oblique or pennate muscle fibres, forming an angle with the direction of the muscle movement. The angle is greater in the young population and physically active people [13, 14]. The morphology of the muscles, including the muscle or muscle group thickness, muscle fibre length, and the angle with respect to the aponeurosis can be evaluated with an ultrasound. [15].

A number of studies evaluated the relationship between the muscle parameters that can be measured by an ultrasound with the age, sex, body physical condition, and different diseases and syndromes. There are also studies that compare the ultrasound parameters, including the muscle thickness, CSA, muscle fibres length, and echo-intensity to different functional parameters and tests for skeletal muscle mass recommended by the EWGSOP [16-28]. However, studies exploring correlation between muscle or muscle group thickness and total skeletal muscle mass values established by measuring the CSA of the muscles on axial CT slices have not been conducted yet. There are also no studies investigating possible correlation between the oblique (pennation) angle of m. rectus femoris and muscle strength and physical performance tests.

AIM OF THE STUDY

To assess whether the ultrasound measurement of m. rectus femoris and m. gastrocnemius medialis can be used as a biomarker for diagnosis of reduced muscle mass, muscle strength, and physical performance in sarcopenia.

MATERIALS AND METHODS

Study design: Prospective, cross-sectional, case-control study.

Participants: Eighty patients who underwent abdominal CT for diagnostic purposes in February, March, and April 2019 in our centre, aged 20 to 89 years, with a mean age of 60 years and 3 months (SD=14.1) were included.

Inclusion criteria: Consecutive patients aged 20 or above that signed the informed consent of the study.
Exclusion criteria: Below 20 years of age, neuromuscular disorders, peripheral neuropathies, acute or chronic trauma, or other acute or chronic diseases that could affect the handgrip strength test. Impossibility of independent walk due to any cause that could affect the gait speed test. Severe dementia or similar disorders that could affect the possibility of understanding the informed consent. Diseases causing diffuse soft-tissue oedema that can affect measuring the CSA of abdominal muscles or the echo intensity of muscles of the distal extremity.

Methods:
After obtaining demographic data, the height of the participant in centimetres, and body mass in kilograms are measured, with accuracy of 0.1 kg. In our study, we use the criteria for muscle mass and function evaluation and diagnosis of sarcopenia recommended by EWGSOP, as well as tests and measurements proposed by the same group.

CT measurement of muscle mass
All CT exams are completed by a 64-detector Siemens SOMATOM Definition AS CT machine. The technique for single-slice assessment of total skeletal muscle mass described by Derstine et al in 2018 was used [11]. The summed cross-sectional area of all muscles on single 3 mm thick axial slice at the L3 vertebral body level were measured. ImageJ biomedical software, freely assessable on the internet, was used to measure the muscle CSA. All muscles were manually marked on a selected slice with great care, to avoid soft-tissue surrounding organs. Threshold values between -29 and 150 Hounsfield Units (HU) were applied to avoid measurement of intermuscular fat tissue. CSA cut-off values for reduced muscle mass diagnostic for sarcopenia were set to 92.2 cm² for women and 144.4 cm² for men (Fig. 1).

Measurement of muscle strength
A handgrip strength test using a hand dynamometer was used to measure muscle strength (the moment of strength). The participant is standing, holding one arm in a vertical position, the forearm horizontally positioned, and the elbow in a 90-degrees flexion.
The hand holding the dynamometer is in a neutral position. The participant presses the dynamometer with a maximal possible force for 5 seconds, using the dominant hand. Three measurements were made for each participant and a mean value was obtained. Values lower than 26 kg for men and 16 kg for women were considered diagnostic for sarcopenic low muscle strength.

**Measurement of physical performance**

A 4-metre normal gait speed test was used to measure physical performance. The participant is walking with his/her normal walking speed between a starting and a finishing point. The 6-meter distance was marked. The measurement begins at 1 meter after the start and ends 1 meter before the finish line, to avoid including the patient’s acceleration and deceleration measurements. Three measurements were performed for each patient and mean values were obtained. Values below 0.8 meters per second were considered diagnostic for sarcopenic low physical performance.

**Diagnosis of sarcopenia**

Muscle mass reduction, assessed with CT values for skeletal muscle mass, together with low muscle strength or low physical performance established with the gait speed test and the handgrip strength test, were considered diagnostic for sarcopenia.

**Ultrasound measurements**

After finishing all other tests, ultrasound measurements were completed. All measurements were performed with a Siemens Acuson X-300 machine, using high-frequency linear transducer 5-13 MHz (VF-13.4). Patients were positioned supine, with the hip in a neutral position and the knee in extension, and asked to remain relaxed and avoid muscle contraction during the exam. The measuring point was set at half distance of the line connecting the anterior superior iliac spine and the upper patellar pole. Thickness of the rectus femoris muscle (RFD) expressed in millimetres was measured in transverse plane. Muscle thickness was assessed at the middle part of the muscle, between the superficial and deep aponeurosis (Fig. 2a and 2b).

![Fig. 2a and 2b. Rectus femoris muscle in transverse plane in normal individual (a) and patient with severe sarcopenia (b). Measurement of muscle thickness is performed at the middle part of the muscle (vertical line), between the superficial and deep aponeurosis](image-url)
Oblique (pennation) angle is the angle formed by the oblique muscle fibres of the rectus femoris muscle and the deep aponeurosis. Measurement of the rectus femoris muscle angle (RFA) was performed in longitudinal plane, at the lateral half of the muscle. Three measurements were taken and the mean value was calculated. Echo intensity of the same muscle (ERF) was measured using ImageJ software, from transverse images obtained for previous measurements. Mean intensity of the pixels of the region of interest which included most of the rectus femoris CSA was assessed. The values were expressed in numbers (Fig. 3).

Fig. 3. Rectus femoris muscle in transverse plane. Measurement of echo intensity of the muscle is performed within the region of interest (yellow line), containing all visible muscle parts, excluding the aponeuroses and intermuscular fat tissue.

The patient was then turned prone with the knee in extension and the foot hanging freely at a 90-degree angle. The measurement point was set at the junction of the proximal and middle third of the line connecting the popliteal groove and the tip of the lateral malleolus. The thickness (GMD), the pennation angle (GMA) (Fig. 4a and 4b), and the echo intensity (EGM) of the medial head of the gastrocnemius muscle were measured using the same protocol used for the measurements of the rectus femoris muscle.
Muscle thickness, pennation angle and echo-intensity of rectus femoris and gastrocnemius medialis muscle measured by ultrasound as biomarkers for sarcopenia

Statistical analysis
The collected data was evaluated using the SPSS 21 statistical software. Correlations between rectus femoris and gastrocnemius muscle thickness, pennation angle, and echo intensity on the one hand, and muscle mass, muscle strength, and performance tests proposed by the EWGSOP on the other, were assessed with the Pearson correlation test. ANOVA was used to assess the significance of the differences between the variables.

RESULTS
The mean values, the minimal and maximal values, and the standard deviations for biometrical parameters, the data obtained from muscle strength, physical performance test, and the values for total skeletal muscle mass acquired with CT CSA measurements for male and female participants separately are summarized in Table 1.

Table 1- Descriptive statistics for the minimal, maximal values, standard deviation for age, height, body mass, handgrip strength test, gait speed test and muscle cross-sectional area CSA at L3 vertebral level in male and female participants.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Height</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Mass</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Gait speed</td>
<td>6</td>
<td>3.09</td>
</tr>
<tr>
<td>Handgrip</td>
<td>6</td>
<td>0.35</td>
</tr>
<tr>
<td>CSA</td>
<td>6</td>
<td>2.55</td>
</tr>
</tbody>
</table>
Values for the rectus femoris pennation angle (RFA), the gastrocnemius medialis angle (GMA), the echo intensity of the same muscles (ERF and EGM), and the thickness of the same muscles (RFD and GMD) are presented in Table 2. All mean values were higher for men compared to women. ANOVA showed significantly different values for RFA, ERF, and RFD, but not for GMA, GMD, and EGM.

**Table 2**- Descriptive statistics for minimal, maximal and mean values and standard deviation for rectus femoris and gastrocnemius medialis muscle thickness (RFD, GMD), pennation angle (RFA, GMA) and echo intensity (ERF, EGM) in male and female participants.

| Variable | Male | | | Male | | | | Female | | | |
|----------|------|---|---|------|---|---|---|------|---|---|---|---|---|
|          | N    | Mi. n. | Max. | Mean | Std. Dev. | N    | Mi. n. | Max. | Mean | Std. Dev. |
| RFA      | 8    | 8.5    | 15.  | 11.  | 1.5       | 3    | 7.9    | 15.  | 11.  | 1.3       |
| GMA      | 8    | 14.    | 22.  | 17.  | 1.6       | 3    | 14.    | 22.  | 17.  | 1.2       |
| ERF      | 8    | 13.    | 69.  | 34.  | 11.       | 3    | 15.    | 76.  | 41.  | 11.       |
| EGM      | 8    | 11.    | 66.  | 35.  | 11.       | 3    | 14.    | 74.  | 38.  | 11.       |
| RFD      | 8    | 13.    | 80.  | 22.  | 4.5       | 3    | 11.    | 48.  | 19.  | 3.6       |
| GMD      | 8    | 9.2    | 58.  | 18.  | 5.6       | 3    | 10.    | 48.  | 18.  | 5.1       |

The Pearson correlation (Table 3) showed statistically significant moderate or strong correlation between all ultrasound variables and CSA in men, except for GMD, where the correlation was weak. Pearson correlation showed moderate or strong correlation between all ultrasound variables and CSA in women, except for GMD, where the correlation was not significant. There was significant correlation between muscle thicknesses and gait speed and handgrip strength test, except for GMD and handgrip strength test in women. Significant negative correlation between the gait speed test and the pennation angle of both muscles in both sexes was seen. There was significant positive correlation between the handgrip strength and the echo intensity in both measured muscles in both sexes.

**Table 3**- Pearson correlation between the ultrasound variables and muscle cross-sectional area (CSA) at L3 vertebral level, muscle density, gait speed test and handgrip strength in men and women.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Variable</th>
<th>RFA</th>
<th>GMA</th>
<th>ERF</th>
<th>EGM</th>
<th>RFD</th>
<th>GMD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>CSA</td>
<td>.659*</td>
<td>.495*</td>
<td>-.610*</td>
<td>-.555*</td>
<td>.756*</td>
<td>.383*</td>
</tr>
<tr>
<td></td>
<td>Gait speed</td>
<td>-.583*</td>
<td>-.449*</td>
<td>.634*</td>
<td>.498*</td>
<td>-.544*</td>
<td>-.311*</td>
</tr>
<tr>
<td></td>
<td>Handgrip</td>
<td>.715*</td>
<td>.511*</td>
<td>-.699*</td>
<td>-.614*</td>
<td>.693*</td>
<td>.325*</td>
</tr>
<tr>
<td>Female</td>
<td>CSA</td>
<td>.547*</td>
<td>.517*</td>
<td>-.471*</td>
<td>-.402*</td>
<td>.638*</td>
<td>.288</td>
</tr>
<tr>
<td></td>
<td>Gait speed</td>
<td>-.714*</td>
<td>-.450*</td>
<td>.517*</td>
<td>.457*</td>
<td>-.490*</td>
<td>-.347*</td>
</tr>
<tr>
<td></td>
<td>Handgrip</td>
<td>.411*</td>
<td>.294*</td>
<td>-.462*</td>
<td>-.447*</td>
<td>.470*</td>
<td>.276</td>
</tr>
</tbody>
</table>
Eighteen male and 14 female participants, or 18.93%, had sarcopenia, according to the criteria by EWGSOP.

ANOVA showed significant difference for ultrasound variables between the participants aged 65 or above with and without sarcopenia, except for GMD and EGM in women. (Table 4). Age difference between the groups was not statistically significant (p > 0.05).

**Table 4**-ANOVA for significance of differences between rectus femoris and gastrocnemius medialis muscle thickness (RFD, GMD), pennation angle (RFA, GMA) and echo intensity (ERF, EGM) in male and female patients, with and without sarcopenia, aged 65 or above.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig.</th>
<th>Variable</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>RFA</td>
<td>51.694</td>
<td>64.508</td>
<td>.000</td>
<td>RFA</td>
<td>22.422</td>
<td>38.443</td>
<td>.000</td>
</tr>
<tr>
<td>GMA</td>
<td>35.259</td>
<td>32.910</td>
<td>.000</td>
<td>GMA</td>
<td>7.837</td>
<td>9.685</td>
<td>.010</td>
</tr>
<tr>
<td>ERF</td>
<td>1321.068</td>
<td>17.411</td>
<td>.002</td>
<td>ERF</td>
<td>872.544</td>
<td>9.397</td>
<td>.023</td>
</tr>
<tr>
<td>EGM</td>
<td>1183.636</td>
<td>13.198</td>
<td>.001</td>
<td>EGM</td>
<td>518.323</td>
<td>4.307</td>
<td>.093</td>
</tr>
<tr>
<td>RFD</td>
<td>513.191</td>
<td>54.829</td>
<td>.000</td>
<td>RFD</td>
<td>208.769</td>
<td>32.143</td>
<td>.000</td>
</tr>
<tr>
<td>GMD</td>
<td>377.795</td>
<td>10.126</td>
<td>.007</td>
<td>GMD</td>
<td>88.646</td>
<td>2.003</td>
<td>.227</td>
</tr>
</tbody>
</table>

**DISCUSSION**

Results about RFD, RFA, ERF, GMA, and EGM show significant correlation with CSA values. A number of studies confirm there is a strong correlation between the CSA and the total skeletal muscle mass and muscle volume of the whole body [29-31]. A CSA at L3 vertebral level is a mortality and morbidity predictor in various patient groups [32, 33]. EWGSOP recommends CT as a method for total skeletal muscle mass evaluation [4]. In a study evaluating 27 volunteers, Scott et al compared CSA values of the quadriceps femoris muscle and the gastrocnemius muscle obtained with panoramic ultrasound and axial MR images. There was high sensitivity and specificity between the two methods for quadriceps femoris CSA, but low specificity for the gastrocnemius muscle [34]. Similarly, our results confirm that RFT has a potential to be used as a biomarker for assessment of total muscle mass, as well as muscle mass evaluation in sarcopenic patients and in diagnosis of sarcopenia. There is a weak correlation between GMD and CSA in men and no correlation in women.

Significant positive correlation between all measured ultrasound variables and gait speed test is observed. Muscle architecture, including muscle thickness, pennation angle, and echo intensity, which are all measurable sonographically, is connected to muscle function [26, 35]. A normal gait speed test is proven to have predictive values for the assessment of general health condition and can be used as an indicator for functionality in the elderly or people with chronic diseases. [36]. Because significant negative correlation between RFA and GMA and the gait speed test exists, measurements of both angles can be used as a significant indicator for physical performance. Numerous studies have compared the echo intensity of both muscles with functional parameters and muscle quality and established similar results [19, 22, 24-28]. ERF and EGM also correlate moderately or strongly with the gait speed test and can be used as biomarkers for evaluation of physical performance.

The handgrip strength test using a hand dynamometer is a predictor of risk for morbidity and mortality in the elderly and a general indicator of a person’s health [37].

It is expected that muscle quality will be the main criterion for diagnosis of sarcopenia in the near future, with expected technical and scientific advances. Muscle quality is defined as the muscle force or muscle power against muscle mass (CSA or thickness) [38]. Correlation between the handgrip strength test and the ultrasound values, especially for RFA, RFD, ERF and EGM shows that ultrasound can be used as a method for muscle quality assessment.
All measured ultrasound variables or biomarkers for the rectus femoris muscle show correlation with tests for muscle strength and performance suggested by the EWGSOP. Nevertheless, measurement of the pennation angle and echo intensity is greatly dependable on the patient’s position, the positioning and angulation of the transducer, the state of the muscle (totally relaxed or partially contracted), and the exact part of the muscle being measured. Specific training and knowledge by the operator is needed to obtain adequate results. Measurement of the rectus femoris thickness on the other hand is a very simple and precise method, and it can be easily performed by any examiner familiar with the ultrasound technique. Moreover, the correlation with suggested tests for sarcopenia is higher. That is why it can be suggested as a universal and simple method for evaluating total skeletal muscle mass and physical performance. Measurement of RFA, GMA, ERF, and EGM in clinical settings can be very useful for evaluating muscle strength, performance, and mass, especially in unusual cases, such as unusually tall or short patients.

About 18.93% of the examinees had sarcopenia, 18 men and 14 women, diagnosed using the recommendations of the EWGSOP. The number of patients with sarcopenia in this study is greater compared to individuals with sarcopenia in the general population [6, 7, 8]. The reason for the result is most probably due to the specific group examined in the study. Large numbers of the patients that come for a CT exam in our institution have malignant diseases. Muscle loss is pronounced due to the effect of the tumour itself or the effects of chemotherapy. Another group of patients have long-lasting chronic inflammatory, autoimmune, or other chronic diseases that also affect muscle mass or strength. Secondary sarcopenia in the study group is the most probable reason for greater percentage of sarcopenia compared to the healthy population.

ANOVA showed statistically significant differences between patients with sarcopenia and patients aged 65 or more without sarcopenia, for ultrasound variables, except for GMD and EGM in women. The age of 65 or more was chosen because sarcopenia primarily affects individuals above 65 years, and the age difference between the groups was not statistically significant. Results show that RFD, ERF, and RFA can be used as biomarkers for diagnosing reduced muscle mass, physical performance, and muscle strength in both sexes. In addition, EGM and GMA can be used for estimation of muscle strength and performance in both men and women. More studies with healthy population aged 20-40 years are needed in order to obtain ultrasound cut-off values for sarcopenia.

The study has several limitations. The majority of the participants are not healthy individuals but patients with malignant or other chronic diseases, which could affect ultrasound measurements. A study including larger population is needed in order to obtain more credible and more accurate data. A single examiner took all the measurements, thus assessment of reliability of the method is required.

**CONCLUSION**

An ultrasound of the rectus femoris muscle is a good method for evaluating muscle mass and function in sarcopenia. Measurement of the rectus femoris muscle thickness has a potential of becoming a universal test for total skeletal muscle mass and muscle function measurement.

Measurement of the pennation angle of the rectus femoris or the gastrocnemius medialis muscle can improve the accuracy by obtaining additional results for physical performance, whereas echo intensity measurement of the same muscle can provide results for muscle strength.

Ultrasound can be used for examinations in different settings, such as at the spot of the injury, in a hospital bed, or at the intensive care unit with identical precision.
Due to its availability in almost any larger medical centre, its easiness-to-use, low cost, and possibility of detailed evaluation of superficial tissues of the extremity with greater resolution than any other imaging modality, it could be an ideal method for diagnosis and quantification of sarcopenia.

REFERENCES
Muscle thickness, pennation angle and echo-intensity of rectus femoris and gastrocnemius medialis muscle measured by ultrasound as biomarkers for sarcopenia


ORIGINAL ARTICLE

FACTORS INFLUENCING THE EARLY POSTOPERATIVE QUALITY OF LIFE IN PATIENTS TREATED SURGICALLY FOR GYNECOLOGICAL MALIGNANCIES

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ABSTRACT

Aim: To evaluate the influence of inherent patient characteristics on early postoperative QoL in patients treated surgically for gynecological malignancies

Materials and methods: The study was designed as a prospective cohort study. Patients scheduled for surgical treatment of a gynecological malignancy at the Department of gynecological oncology at the University Clinic of Gynecology and Obstetrics in Skopje, in the period January – December 2018. Quality of life was quantified using a standardized and validated questionnaire (FACT-G) preoperatively and 1 month after surgical treatment. We explored the effect of the following variables: age, BMI, nationality, education, marital status, place of residence, employment, primary location of the neoplasm, disease stage, extent of surgical resection, comorbidities and smoking.

Results: Data from 123 patients were included in the final analysis. The average age of patients at the time of recruitment was 58±10 years (range 23-79 years). Eighty-four patients (68.29%) had endometrial cancer, 22 (17.89%) patients had cervical cancer, while 17 (13.82%) patients had ovarian cancer. Postoperative FACT-G scores were significantly lower (p=0.015). A clinically relevant postoperative decrease in quality of life was identified in 51 patients (41.5%). Independent predictors of deteriorated postoperative QoL in this study were: advanced disease stage, extensive surgical resection, comorbidities and higher education.

Conclusion: The results illustrate the physical, psychological, and social effects of the surgical treatment on the early postoperative QoL, thereby emphasizing the need for a comprehensive, multidisciplinary approach to the pre and postoperative care of these patients.

Key words: quality of life, gynecologic malignancies, FACT-G, surgical treatment.

BACKGROUND

Gynecologic malignant neoplasms make up 18% of all malignant diseases in the female population [1] and are associated with significant morbidity and mortality. The most common gynecologic malignancies are endometrial cancer (53%), ovarian cancer (25%) and cervical cancer (14%) [2]. Cervical cancer is most common in pre- and perimenopausal patients, while endometrial and ovarian malignancies are encountered more frequently in postmenopausal patients. Vulvar malignancies, as well as gestational trophoblastic neoplasms are rare clinical entities.
Factors influencing the early postoperative quality of life in patients treated surgically for gynecological malignancies

The diagnosis of a gynecologic malignancy undoubtedly has severe implications on the life of the patient mainly due to the insecurity, the consequential reorganizing of roles in the family/workplace, the financial burden and the ever-looming possibility of recurrences and/or development of secondary malignant neoplasms [3-5]. Furthermore, these patients undergo a combination of surgery and/or adjuvant chemotherapy and/or radiotherapy, which have additional short-term and long-term detrimental effects on the health-related quality of life (QoL).

The advances in the prevention, early detection and treatment of these diseases in the developed countries, has led to an increase in the rates of survival for most gynecologic malignancies in the past couple of decades. For most of these patients, gynecologic malignancies have become chronic conditions that affects them for a number of years, which emphasizes the importance of QoL and its improvement.

The QoL concept gains more focus in the scientific community during the late 20th century [6]. Traditional clinical outcome measures, such as disease-free survival (DFS) and progression-free survival (PFS), undoubtedly play a pivotal role in guiding the treatment in gynecologic oncology patients. Nevertheless, published data [7,8] suggests that there are treatment modalities with similar survival outcomes, but significantly different effects on QoL, which makes QoL an important outcome measure when determining the optimal treatment strategy in these patients.

The evaluation of quality of life provides additional information from the patients’ perspective related to the disease burden and treatment effectiveness. QoL is a multidimensional dynamic concept reflecting the patient’s subjective perception of the influence of the disease and the associated treatment [9, 10]. The concept incorporates changes in physical, social, emotional and functional wellbeing that can present at any time beginning at moment the patient is diagnosed, during the treatment and long after the patient has finished the treatment [11-13].

Published data concerning the potential factors influencing the QoL in patients with gynecologic malignancies is scarce, especially for patients in the Republic of North Macedonia. Due to the high prevalence rates and the burden associated with the diagnosis of a gynecologic malignancy and/or the associated medical treatment, factors that could potentially influence the QoL of these patients represent an important research topic.

AIM

The aim of the study was to determine the perioperative change in QoL in patients undergoing surgical treatment for a gynecologic malignancy, as well as to identify potential predictive factors associated with a clinically-relevant decrease in QoL 30 days after surgery.

MATERIALS AND METHODS

The study was designed as a prospective cohort study and was conducted at the Department of gynecologic oncology at the University clinic of gynecology and obstetrics, University “Ss. Cyril and Methodius”, Skopje, Republic of North Macedonia. Eligible consecutive patients scheduled for surgical treatment at the Department between January and December 2018 were approached for participation in the study. Inclusion criteria were: presence of a histologically verified cervical or endometrial cancer or a pelvic mass preoperatively assessed as malignant and no previous history of treatment for any kind of malignancy. Exclusion criteria were: any contraindication for surgery and cases in which postoperative histopathology revealed a benign condition or a malignancy of non-gynecologic origin.
The main endpoint of the study was the postoperative change in quality of life, measured by the Functional Assessment of Cancer Therapy-General (FACT-G) score [11], version 4. The FACT-G questionnaire consists of 27 questions, grouped in four domains: physical well-being (PWB), social well-being (SWB), emotional well-being (EWB) and functional well-being (FWB). The PWB, SWB and FWB domains have 7 questions and score 0-28, while EWB has 6 questions and scores 0-24. The answers in the FACT-G questionnaire are formulated as a 5 point Likers scale (0—“not at all” to 4—“very much”), and the values are summed up to form a total score of 0-108.

The questionnaire was translated in Macedonian and was self-administered by the patients, with a researcher available, should the patient have any questions or issues.

To assess the postoperative change in the quality of life, the study used the “minimally important difference” (MID) concept [14]. The MID concept is defined as the lowest difference in the overall score or any domain sub-score that is perceived by the patient as an improvement or deterioration, consequently influencing the management of the patient [14]. The study employed a distribution-based method to calculate MID. For the purposes of this study, QoL one month post-surgery was categorized as “deteriorated” if the postoperative FACT-G (or relevant domain) score was at least 5 points lower than the preoperative score (MID=5).

We also recorded and analyzed the following variables: body mass index (BMI), nationality, degree of education (high school or lower vs. university degree), marital status (married/living with a partner vs. divorced/widowed), place of residence (urban vs. rural), primary neoplasm location (cervix/endometrium/ovary), disease stage (early vs. advanced), extent of surgical resection, comorbidities and smoking. Patients were classified in three age groups 46-64, <46 and >64 years. BMI was classified in accordance with the World Health Organization BMI classification. Surgical procedures were classified as “extensive” if they included any of the following: systematic pelvic lymph node dissection, parametrectomy, peritonectomy, infracolic omentectomy, bowel resection with or without diversion and urinary diversion. The following comorbidities were recorder: diabetes, history of a major thrombotic event, chronic renal failure, history of immunosuppression and chronic cardio-vascular conditions (excluding hypertension).

**Statistical analysis**

The data was digitized and entered into a database. The statistical analysis was carried out using the SPSS statistical software package version 23 (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.)

Standard descriptive statistics were done and data was displayed using frequencies, percent, mean and standard deviation (SD), where appropriate. The difference in the FACT-G score and the associated domains pre- and postoperatively were compared using the Student’s T test for independent samples. Patients were then classified in groups based on the MID for the postoperative FACT-G score: a group of patients with clinically significant postoperative deterioration of QoL and a group of patients with identical/improved postoperative QoL. The differences in the distributions of the listed categorical variables in the two groups of patients were tested using the Chi square test and Fisher’s exact test, depending on the group size.

Logistic regression analysis was carried out to determine and evaluate potential predictors of postoperative clinically significant deteriorated QoL. The predictors identified as significant by the univariate analysis were subsequently analyzed in a multivariate regression model. Variables were entered in the regression models at a probability of p<0.05 and were removed from the models at p>0.1. A value of p<0.05 was considered statistically significant.
RESULTS

A total of 136 patients were approached for participation, 13 of which were excluded from the final statistical analysis: 4 patients (2.9%) where postoperative histopathology revealed malignancies of non-gynecologic origin, 7 patients (5.2%) with incomplete questionnaires, 1 patient (0.7%) which was unavailable for evaluation one month after surgery and one patient (0.7%) due to a lethal outcome in the early postoperative period. The remaining 123 patients (90.4%) were selected for analysis.

The average age of patients participating in this study was 58±11 years, and the average BMI was 31.6±7.1. The majority of the patients had high-school level of education or lower (n=110, 89.4%), were of Macedonian nationality (n=87, 70.7%), were married/living with a partner (n=106, 86.2%). Over half of the patients had their own income (n=77, 62.6%), while 46 patients (37.4%) were unemployed. Fifty-two patients (42.3%) had at least one comorbidity, and the vast majority (n=110, 89.4%) were non-smokers. Table 1 summarizes the demographic and clinical characteristics of the patients included in the study.

The average value for the preoperative FACT-G score was 82.4±18.7, while postoperatively the average FACT-G score was 80.5±21.8 (Table 2). The analysis revealed a statistically significant difference between the pre- and postoperative FACT-G scores, as well as the physical and functional well-being domain scores. MID for a postoperatively deteriorated QoL was verified in 51 patients (41.5%).

Postoperative deterioration of QoL was statistically significantly more frequent in patients younger than 46 years and older than 64 year (p=0.004), patients with higher education (p=0.04), patients with advanced stage disease (p<0.001), patients undergoing extensive surgical procedures (p<0.001) and patients with at least one comorbidity (p=0.003, Table 3).

The univariate logistic regression analysis revealed five potential predictors of postoperative QoL deterioration: age >64 years, higher education, advanced stage disease, extensive surgical resection and comorbidities (Table 4). The age, however, lost its independence as a predictor in the multivariate analysis. with the following four factors being independent predictors of postoperative QoL deterioration: higher education (OR=7.76, p=0.024), advanced disease stage (OR=21.77, p<0.001), extensive surgical resection (OR=5.5, p=0.005) and comorbidities (OR=3.75, p=0.034).
Table 1. Demographic and clinical characteristics of the patients included in the study

<table>
<thead>
<tr>
<th>Category</th>
<th>n=123</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age group, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>46-64</td>
<td>75 (61%)</td>
</tr>
<tr>
<td>&lt;46</td>
<td>12 (9.8%)</td>
</tr>
<tr>
<td>&gt;64</td>
<td>36 (29.3%)</td>
</tr>
<tr>
<td><strong>Categorized BMI, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Normal BMI</td>
<td>18 (14.6%)</td>
</tr>
<tr>
<td>Pre obesity</td>
<td>39 (31.7%)</td>
</tr>
<tr>
<td>Obesity class I</td>
<td>36 (29.3%)</td>
</tr>
<tr>
<td>Obesity class II</td>
<td>18 (14.6%)</td>
</tr>
<tr>
<td>Obesity class III</td>
<td>12 (9.8%)</td>
</tr>
<tr>
<td><strong>Degree of education, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>High school or lower</td>
<td>110 (89.4%)</td>
</tr>
<tr>
<td>University diploma</td>
<td>13 (10.6%)</td>
</tr>
<tr>
<td><strong>Nationality, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Macedonian</td>
<td>87 (70.7%)</td>
</tr>
<tr>
<td>Albanian</td>
<td>22 (17.9%)</td>
</tr>
<tr>
<td>Turkish</td>
<td>8 (6.5%)</td>
</tr>
<tr>
<td>Toma</td>
<td>3 (2.4%)</td>
</tr>
<tr>
<td>Bosnian</td>
<td>3 (2.4%)</td>
</tr>
<tr>
<td><strong>Marital status, n(%)</strong></td>
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</tr>
<tr>
<td>Married/living with a partner</td>
<td>106 (86.2%)</td>
</tr>
<tr>
<td>Divorced/widowed</td>
<td>17 (13.8%)</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
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</tr>
<tr>
<td>Employed/retired</td>
<td>77 (62.6%)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>46 (37.4%)</td>
</tr>
<tr>
<td><strong>Place of residence</strong></td>
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</tr>
<tr>
<td>Urban community</td>
<td>82 (66.7%)</td>
</tr>
<tr>
<td>Rural community</td>
<td>41 (33.3%)</td>
</tr>
<tr>
<td><strong>Primary location of the neoplasm</strong></td>
<td></td>
</tr>
<tr>
<td>Endometrium</td>
<td>84 (68.3%)</td>
</tr>
<tr>
<td>Cervix</td>
<td>22 (17.9%)</td>
</tr>
<tr>
<td>Ovary</td>
<td>17 (13.8%)</td>
</tr>
<tr>
<td><strong>Disease stage</strong></td>
<td></td>
</tr>
<tr>
<td>Early</td>
<td>98 (79.7%)</td>
</tr>
<tr>
<td>Advanced</td>
<td>25 (20.3%)</td>
</tr>
<tr>
<td><strong>Extensive surgical resection</strong></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>77 (62.6%)</td>
</tr>
<tr>
<td>Yes</td>
<td>46 (37.4%)</td>
</tr>
<tr>
<td><strong>Comorbidities</strong></td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td>71 (57.7%)</td>
</tr>
<tr>
<td>Present</td>
<td>52 (42.3%)</td>
</tr>
<tr>
<td><strong>Smoking</strong></td>
<td></td>
</tr>
<tr>
<td>Non-smoker</td>
<td>110 (89.4%)</td>
</tr>
<tr>
<td>Smoker</td>
<td>13 (10.6%)</td>
</tr>
</tbody>
</table>
Factors influencing the early postoperative quality of life in patients treated surgically for gynecological malignancies

Table 2. Comparison of Pre- and postoperative FACT-G and domain scores

<table>
<thead>
<tr>
<th></th>
<th>Preoperative (mean ±SD)</th>
<th>Postoperative (mean. ±SD)</th>
<th>p†</th>
</tr>
</thead>
<tbody>
<tr>
<td>FACT-G</td>
<td>82.4±18.7</td>
<td>80.5±21.8</td>
<td>0.016†</td>
</tr>
<tr>
<td>PWB</td>
<td>22.2±5.5</td>
<td>21.4±6.3</td>
<td>0.002*</td>
</tr>
<tr>
<td>SWB</td>
<td>21.6±4.9</td>
<td>21.4±5.6</td>
<td>0.226</td>
</tr>
<tr>
<td>EWB</td>
<td>19.1±5.3</td>
<td>18.9±6</td>
<td>0.571</td>
</tr>
<tr>
<td>FWB</td>
<td>19.5±5.4</td>
<td>18.9±6.2</td>
<td>0.011†</td>
</tr>
</tbody>
</table>

†t-test for independent samples; *statistically significant difference.

Table 3. Comparison of patients with deteriorated and identical/improved postoperative QoL (based on MID) – univariate analysis

<table>
<thead>
<tr>
<th>Postoperative QoL (based on MID)</th>
<th>Identical/improved n=72</th>
<th>Deteriorated n=51</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age group, n (%)</td>
<td></td>
<td></td>
<td>0.004†</td>
</tr>
<tr>
<td>46-64</td>
<td>52 (69.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;46</td>
<td>7 (58.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;64</td>
<td>13 (36.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cathegorized BMI, n (%)</td>
<td></td>
<td></td>
<td>0.581†</td>
</tr>
<tr>
<td>Normal BMI</td>
<td>12 (66.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre obesity</td>
<td>23 (59%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obesity class I</td>
<td>23 (63.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obesity class II</td>
<td>9 (50%)</td>
<td></td>
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<tr>
<td>Obesity class III</td>
<td>5 (41.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Degree of education, n (%)</td>
<td></td>
<td></td>
<td>0.04‡</td>
</tr>
<tr>
<td>High school or lower</td>
<td>68 (61.8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>University diploma</td>
<td>4 (30.8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nationality, n (%)</td>
<td></td>
<td></td>
<td>0.992†</td>
</tr>
<tr>
<td>Macedonian</td>
<td>50 (57.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albanian</td>
<td>13 (59.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Turkish</td>
<td>5 (62.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toma</td>
<td>2 (66.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bosnian</td>
<td>2 (66.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marital status, n(%)</td>
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<td>0.609‡</td>
</tr>
<tr>
<td>Married/living with a partner</td>
<td>63 (59.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Divorced/widowed</td>
<td>9 (52.9%)</td>
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<tr>
<td>Employment status</td>
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<tr>
<td>Employed/retired</td>
<td>43 (55.8%)</td>
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<tr>
<td>Unemployed</td>
<td>29 (63%)</td>
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</tr>
<tr>
<td>Place of residence</td>
<td></td>
<td></td>
<td>0.561‡</td>
</tr>
<tr>
<td>Urban community</td>
<td>46 (56.1%)</td>
<td></td>
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</tr>
<tr>
<td>Rural community</td>
<td>26 (63.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary location of the neoplasm</td>
<td></td>
<td></td>
<td>0.551†</td>
</tr>
<tr>
<td>Endometrium</td>
<td>50 (59.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cervix</td>
<td>14 (63.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ovary</td>
<td>8 (47.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease stage</td>
<td></td>
<td></td>
<td>&lt;0.001‡</td>
</tr>
<tr>
<td>Early</td>
<td>70 (71.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advanced</td>
<td>2 (8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extensive surgical resection</td>
<td></td>
<td></td>
<td>&lt;0.001‡</td>
</tr>
<tr>
<td>No</td>
<td>56 (72.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>16 (34.8%)</td>
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<tr>
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<td>0.003‡</td>
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<td>22 (42.3%)</td>
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<tr>
<td>Smoking</td>
<td></td>
<td></td>
<td>1‡</td>
</tr>
<tr>
<td>Non-smoker</td>
<td>64 (58.2%)</td>
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<td></td>
</tr>
<tr>
<td>Smoker</td>
<td>8 (61.5%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

†Chi-square test; ‡Fischer’s exact test
<table>
<thead>
<tr>
<th>Potential predictors</th>
<th>Univariate model</th>
<th>Multivariate model</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (95%CI)</td>
<td>p</td>
</tr>
<tr>
<td>Age group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;46</td>
<td>1.62 (0.46-5.62)</td>
<td>0.452</td>
</tr>
<tr>
<td>&gt;64</td>
<td>4 (1.73-9.25)</td>
<td>0.001</td>
</tr>
<tr>
<td>Higher education</td>
<td>3.64 (1.06-12.57)</td>
<td>0.041</td>
</tr>
<tr>
<td>Advanced stage</td>
<td>28.75 (6.35-130.13)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Extensive surgical resection</td>
<td>5 (2.28-10.99)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>3.25 (1.53-6.87)</td>
<td>0.002</td>
</tr>
</tbody>
</table>

†Statistically significant independent predictor

**DISCUSSION**

The study revealed a statistically significant postoperative deterioration of QoL in patients surgically treated for gynecologic malignancies. Clinically significant deterioration of QoL, as measured by the FACT-G score, was verified in 41.5% of the patients, postoperatively. No statistically significant differences were observed for the social and emotional well-being, 30 days post-surgery. Independent, statistically significant predictors of postoperative deterioration of QoL were advanced disease stage, extensive surgical resection, comorbidities and higher education.

The data from the current study is consistent with most of the published data so far. Lutgendorf et al [15] evaluated 98 patients with early or regionally advanced gynecologic cancer. Their prospective analysis was based on measuring QoL using the FACT-G questionnaire, as well as evaluation of the style of coping with the disease and the overall emotional state of the patient, quantified using corresponding scoring systems and evaluated pre- and one year post-treatment. The most commonly reported issues were sleep disturbances, registered in 40% of the patients, followed by the lack of energy and sexual pleasure. Surprisingly, the medically relevant factors such as disease stage and treatment modality and intensity were not found to be independent predictors of physical well-being 1 year after diagnosis, but were relevant factors during the early stages of the treatment. Nevertheless, the coping strategies contributed significantly for the observed variance in the physical wellbeing of the patients, even after controlling for the medically relevant factors.

The extent of the surgical treatment is closely associated with the stage of the diseases. In spite of that, the extent of surgical resection remained an independent predictor of postoperatively deteriorated QoL in the multivariate analysis. The effect of the severity of the surgical procedure on QoL has been studied in a number of studies. Aljabri et al [16] studied a cohort of 76 patients undergoing major aortic surgery and detected a significant decrease in the physical well-being 5 weeks post-surgery. The extent of surgical resection was found to negatively influence the early postoperative physical well-being in patients surgically treated for gastric and colorectal cancer [17,18], and similar data was published in a longitudinal study of a series of patients with hepatic resections [19]. The statistically significant postoperative deterioration of the physical QoL after extensive surgical procedures could be due to the acute systemic inflammatory response after major surgery, including “sickness behavior” [20] and the unattainability of complete postoperative rehabilitation in certain cases [21].

The current series demonstrated a negative effect of higher education on the postoperative QoL. Identical results were published by Gil et al [22]; in a cohort study of 157 patients with endometrial, cervical and ovarian cancer, the authors published an inverse correlation between the degree of education and the FACT-G score. One possible hypothesis that could explain this is the amount of information at the patients’ disposal: patients with higher education have a better grasp on the severity of their condition, the treatment plan and the expected outcomes.
We did not identify statistically significant differences in the postoperative social and emotional well-being domain scores, which is in line with the data published in studies concerned primarily with the mental aspect of QoL [23, 24]; in these studies, the treatment was not found to influence the postoperative emotional and social QoL in patients undergoing gynecologic surgery. There is, however, a possibility that the lack of change might be due to a postoperative cognitive dysfunction affecting the mental capacity of the patients, a condition often encountered in patients undergoing extensive surgical procedures [25].

This study is limited by the relatively small sample size, therefore all observed differences between the groups of patients with deteriorated and identical/improved postoperative QoL, should be interpreted with caution. The MID concept in the study was used to identify only the subset of patients with deteriorated postoperative QoL, based on the valid evidence that QoL is diminished after surgery [16-19].

CONCLUSION
The surgical treatment of gynecologic malignancies significantly affects the quality of life of patients, evaluated 30 days post-surgery. More than 40% of the patients in the study had a clinically relevant deterioration of postoperative QoL. Independent predictors of deteriorated postoperative QoL in this study were: advanced disease stage, extensive surgical resection, comorbidities and higher education.

The results illustrate the physical, psychological, and social effects of the surgical treatment on the early postoperative QoL, thereby emphasizing the need for a comprehensive, multidisciplinary approach to the pre and postoperative care of these patients. Further studies should facilitate the development of a clinical pathway for the care of women who undergo surgical treatment with curative intent for gynecologic cancer.

DISCLOSURE
The author reports no conflicts of interest in this work

REFERENCES
ORIGINAL ARTICLE

CORRELATION BETWEEN RISK FACTORS FOR ONSET OF DISC HERNIATION AND LOCALIZATION OF THE PATHOLOGIC CHANGE

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¹University Institute of Radiology, Skopje, Republic of North Macedonia; ²University Clinic of Gastroenterohepatology, Skopje, Republic of North Macedonia; ³University Clinic for Neurosurgery, Skopje, Republic of North Macedonia; ⁴GCH “8th of September”, Skopje, Republic of North Macedonia

ABSTRACT
Background: Almost 70% of the population suffers from neck pain at some point during a lifetime. Our aim was to show the impact of the risk factors on the incidence of disc herniation and the localization of the pathology.

Materials and methods: This was a cross-sectional study in which MRI data of the cervical spine and data from the questionnaire designed for the study were used. The focus group consisted of 98 subjects aged 35-70 years with refractory neck pain.

Results: Our study showed that in male subjects 40% of the herniated discs were at level of C3/C4 and C6/C7 respectively, and 47.06% of the herniated discs were at C5/C6 level in female subjects. Sedentary work had a significant impact on the prevalence of cervical disk herniation (Chi-square=16.88; df=3; p=0.00082), most commonly found (46.15%) at C5/C6 level.

Conclusion: Disc herniation is most common in the middle cervical spine (C5/6). Significant predictors for the analyzed risk factors of cervical discs herniation are: age, genetic predisposition and work-related daily slouching or straining the neck.

Keywords: MRI, herniated disc, refractory neck pain, cervical spine, neck

INTRODUCCION

Contemporary life diseases are non-communicable diseases that have become the leading cause of morbidity and mortality in developed countries. This epidemiological shift has taken large proportions in developing countries as well. The causes of chronic non-communicable diseases are complex and prevention has to include many risk factors that contribute to their onset. Neck pain is a very common phenomenon. It affects almost 70% of the population at some point during a lifetime [1]. Medical history is of great help in differentiation of the diverse pathology of the cervical spine. Nature, length and location of the pain, associated numbness or paresthesias in one or both upper extremities, pain duration and length, other musculoskeletal symptoms and past history of previous trauma are of particular importance. One of the main causes of neck pain or cervical syndrome is degenerative cervical spine disease. Studies have shown that almost 20% of asymptomatic patients younger than 40 years have had some form of a degenerative (intervertebral) disc disease [2].

The motive for undertaking this study has been the increasing number of degenerative cervical spinal diseases.

AIMS

The aim of this study was to present the type of degenerative cervical spinal diseases and the direct influence of the risk factors on the onset of these degenerative diseases.
Specific aims:
- To present the sociological characteristics of patients with degenerative spinal diseases (sex, age, working habits);
- To identify the risk factors for the appearance of cervical spine disc herniation;
- To determine the localization of the pathologic change in the cervical spine.

MATERIALS AND METHODS
This was a cross-sectional study conducted at the University Institute of Radiology in Skopje, Macedonia where data of patients’ results were collected and findings were analyzed. MRI data of the cervical spine and specialists’ radiological reports of patients were used as well as data from the questionnaire designed for the purposes of the study.

The focus group consisted of subjects at the age of 35-70 years with refractory neck pain. The examined group included subjects who had a working diagnosis of cervical brachial syndrome or cervical radiculopathy referred to the University Clinic of Radiology in Skopje for MRI of the cervical spine and determination of its pathological changes. Sample size: the examined group consisted of 98 subjects who were referred for MRI to detect cervicobrachial syndrome for the first time.

RESULTS
We have analyzed the correlation between the protrusion degree of cervical intervertebral discs and sex of the subjects, type of their profession and factors associated with their lifestyle (smoking cigarettes and physical inactivity).

There was a non-significant difference between men and women with cervical intervertebral disc degeneration regarding the level at which disc herniation appeared (Chi-square=5.79; df=3; p=0.113). Of 20 diagnosed herniated discs in men, 40% of the protrusions were at C3-C4 level and the same number at C6-C7 level. On the other hand, the largest percentage (47.06%) of herniated discs in women was found at C5-C6 level. Statistical testing of the level of herniated discs between males and females was not significant (X2 =5.97; df=3; p= 0.113).

A non-significant difference was found between subjects with cervical intervertebral disc degeneration whose daily work activities were or were not related to computer use regarding the level at which disc herniation developed (Chi-square=4.98; df=3; p=0.17). Subjects who spent a great deal of working hours using computers more often developed herniated disc at C5-C6 and C6-C7 levels than subjects who did not work with computers (40% vs. 34.48 and 40% vs. 20.69%, respectively).

Fig. 1. Distribution of intervertebral disc protrusion level according to working in sitting position.
Sedentary jobs had a significant influence on the level of cervical spine herniation (Chi-square=16.88; df=3; p=0.00082). The C4-C5 level was most commonly affected by disc herniation (60%) in the group of subjects who did not spend long sitting hours in the workplace, whereas the largest percentage (46.15%) of subjects who had a sedentary job had herniated disc at C5-C6 level. The remaining types of jobs, such as lifting heavy weights every day, jobs involving everyday slouching or straining the neck, work with vibrating machines had no significant influence on the level where cervical spine herniated disc appeared. Subjects with cervical spine degenerative changes, whose job was lifting heavy weights every day, had non-significantly more often herniated disc at C4-C5 in comparison with subjects who did not have that type of work (39.13% vs. 22.58%) (X2=5.38; df=3; p=0.15). Subjects who slouched and strained their neck everyday at their workplace compared to subjects who did not have such jobs had non-significantly more often herniated disc at C3-C4 (4.35% vs. 0%), at C4-C5 (34.78% vs. 0%), or at C6-C7 level (30.43% vs. 25%) (X2 = 6.85; df =3; p=0.077). Both diagnostic protrusions of intervertebral discs (I.V.) of the cervical spine were located at C5-C6 level in subjects who worked with vibrating machines. This segment of the spinal neck was also the most common location for herniated disc (18 – 34.61%) in the group of 52 diagnosed protrusions in patients who did not work with vibrating machines (Fisher’s exact two tailed p=0.374).

Fig. 2. Distribution of intervertebral disc protrusion level according to physical activity.

DISCUSSION
The investigation of the location of cervical spine pathology in Macedonia along with the risk factors for its onset is the first one of this kind in our country. This study has provided data that would be of crucial importance for promotion and improvement of the health as well as for advancement in primary prevention.

The results obtained in this study about the incidence of pathologic changes of I.V. cervical spine in the examined subjects have shown that more than half of the study subjects (50 – 51.02%) had cervical spine I.V. disc herniation to a certain degree. In a population-based study conducted in Rochester, Minneapolis, USA, the average annual incidence per 100,000 population for cervical radiculopathy was 107.3 in males and 63.5 in females. The cause of cervical radiculopathy in 21.9% of the examined patients was intervertebral disc protrusion, whereas in 68.4% a result of spondylosis, disc protrusion or both [3].
Another study about the risk factors also realized in the USA reported 13,000,000 United States military individuals within the Armed Forces affected by cervical radiculopathy, the incidence being 1.79 cases per 1,000 persons on an annual basis. The same study also demonstrated that individuals older than 40 years, female sex and White race had a greater risk of developing cervical radiculopathy [4]. The results of our study have shown that the onset of cervical I.V. disc herniation was significantly dependent on sex of the subjects, and hence a more common finding of these pathologic changes was observed in women. Cervical I.V. disc herniation was found in 18 (36%) male and in 32 (64%) female subjects. Kelley LA. suggested that cervical disc herniation was of almost equal male and female incidence [5]. Marchiori and Henderson noticed that higher incidence of herniated disc was found in females than in males [6]. The same conclusion was presented by Shoenfeld [4]. These results are in agreement with the findings in our study indicating that female subjects are of higher risk of developing cervical disc herniation.

Regarding the results about the influence of the occupational risk factors, cervical I.V. disc herniation was non-significantly associated with computer use, but was significantly associated with the rest of the examined occupational risk factors. Seventy percentages of subjects whose daily work activities were associated with long sitting hours had a positive finding of I.V. disc herniation. Jobs that required everyday lifting heavy weights had a significant influence on the appearance of cervical I.V. disc herniation, which was detected in 42% of the examined subjects involved in this type of work. Also, subjects whose work required everyday slouching and straining the neck were more likely to experience cervical disc herniation (registered in 84% of subjects). In each of the groups with and without herniated disc two subjects who worked with vibrating machines were registered. Behavioral factors analyzed by practicing physical activity were non-significantly associated with cervical I.V. disc herniation. One recent survey performed in Poland has shown that 23-28% of coal miners suffered from neck pain in comparison with 4% found in the control subjects. Degenerative changes in the cervical spine as narrowed intervertebral disc spaces and spondylophytes were found in these coal miners. This proved the direct correlation between occupational factors and spinal degenerative diseases [7]. The results about the influence of the occupational risk factors in our study have demonstrated that they had the largest impact on the onset of cervical disc herniation. Our results have illustrated that cervical I.V. disc herniation was non-significantly associated with computer use, but was significantly associated with sedentary work, everyday lifting of heavy weights, and everyday slouching or straining the neck. In 70% of examined subjects who work in sitting position for long hours, two or several cervical spine disc herniation were observed, whereas this type of pathologic changes were detected in 42% of subjects whose everyday work was lifting heavy weights and in 84% of subjects whose workplace was connected with everyday straining the neck.

It can be concluded from the results obtained in our study that occupations connected with sitting for long hours at the work desk, everyday slouching or straining the neck, work with computers, lifting heavy weights and presence of vibrations during working hours are risk factors for development of degenerative cervical diseases.

In this study we analyzed the correlation of the level of cervical I.V. disc herniation and the demographic characteristics of the examined subjects, as well as the occupational and behavioral factors. The statistical analysis did not confirm influence of the sex on the location of cervical degenerative changes. With reference to the occupational risk factors, there was a positive correlation concerning the level at which I.V. disc herniation developed in those subjects who worked in sitting position in the workplace. In these subjects disc herniation was found at C5-C6 (40%) and at C6-C7 level (40%).
Correlation between risk factors for onset of disc herniation and localization of the pathologic change

Therefore, a conclusion can be drawn that work with personal computers influenced on the development of degenerative cervical I.V. disc diseases, most often as a result of slouched and strained posture with neck extension. Jobs connected with long sitting hours also had a significant influence on the level of cervical I.V. disc herniation. The C4-C5 was the most common level at which disc herniation (60%) appeared in the group of subjects who did not work in sitting position for long hours as opposed to subjects with long sitting hours in the workplace, where the largest percentage (46.15%) had herniated disc at C5-C6 level.

Herniated I.V. disc is predominantly found in younger subjects, that is, subjects under the age of 40 years as opposed to I.V. disc degeneration that is predominantly found in subjects older than 40 years as a result of the natural process of ageing. Subjects older than 40 years are at a higher risk of developing cervical radiculopathy [4]. Genetic predisposition and environmental factors were investigated in the Twin Spine study [8]. It was a multidisciplinary and multinational research project, which had been started in 1991 including collaborators primarily from Canada, Finland and the United States of America. The principal goal of the research was to investigate the etiology and pathogenesis of disc degeneration. Among the most significant findings were the influence of heredity on I.V. disc degeneration and the identification of the first gene forms associated with I.V. disc degeneration. Also, the investigation analyzed the effects of smoking exposure and other important occupational exposures on disc degeneration in identical twins that served as a control group. As a result of this study, today I.V. disc degeneration is considered to be determined by environmental factors, but genetic predisposition plays an important role. In another study conducted in Great Britain, MacGregor et al. examined 1,064 twins with low back or neck pain and concluded that genetic factors rather than environmental factors had larger influence on the onset of these symptoms [9]. In our study genetic predisposition also played an important role in development of pathologic conditions in the cervical spine. In 42% of examined subjects with positive familial history, disc degeneration in some segment of the cervical spine was diagnosed.

We analyzed the association of the cervical spine herniation location regarding demographic characteristics, occupational and behavioral factors. Statistical analysis did not confirm the influence of sex on the level of degenerative cervical I.V. disc herniation. The results obtained showed that in the group of male subjects with diagnosed cervical I.V. disc herniation, 40% had herniated disc at C3-C4 and the same percentage of subjects at C6-C7 level, whereas in 47.06% of female subjects, herniated disc developed at C6-C7 level. In the literature C5-C6 and C6-C7 have been demonstrated as the most common levels at which disc herniation appear regardless of the sex. A statistically significant difference was being registered between groups of subjects who are involved in physical activities and those who are inactive regarding the level of cervical I.V. disc herniation. Subjects who were physically active significantly more often have herniated disc at C4-C5 level (46.67 vs. 8.33).

The remaining occupational or behavioral factors have no influence on the development of cervical I.V. disc herniation.

Recommendations can be drawn from this study concerning the necessity of undertaking measures and actions for health promotion starting from early age related to the problem of cervical intervertebral disc degeneration. These include: regular systematic examinations and establishment of healthy lifestyle among the young population, raising the awareness level of the parents, raising the awareness of the employed and their managerial team about the problem of spinal degenerative diseases, risk factors and inevitability of their prevention, ergonomic changes at the workplaces, creation and continuous work of centers for intensive ergonomic counseling, education and practice.
REFERENCES
ORIGINAL ARTICLE

BACTERIAL INTRAUTERINE INFECTION AND ACUTE INFLAMMATORY CHANGES OF THE PLACENTA, FETAL MEMBRANES AND UMBILICAL CORD

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ABSTRACT

Introduction: Preterm delivery is a clinical syndrome with multifactorial etiology and it is considered to be one of the most challenging issues of contemporary perinatology. Intrauterine infections play one of the leading roles in the development of this clinical entity, but the prevalence of microbial invasion and the type of microorganisms associated with this condition are still a subject of debate.

Material and methods: We conducted a cross-sectional study at the University clinic for obstetrics and gynecology in Skopje. One hundred and fifty (150) patient with clinical signs of preterm delivery between 24⁰-37⁰ g.w. were included. For microbiological analysis, samples were taken using standard cotton swab, from the maternal side of the placenta at the border between the placental disk and fetal membranes. For histopathologic analysis, placentas were collected in transport container and sent to Institute of pathology. Samples for histopathologic analysis were provided from the following zones: border amnion-chorion, chorionic plate, umbilical cord and fetal membranes. The results were considered statistically significant if p<.05.

Results: Microbiological analysis of provided samples showed a presence of bacteria in 61/150 (40.7%) of the patients. Results from the analysis of the inflammatory changes of the placenta, fetal membranes and umbilical cord showed a higher frequency of maternal and fetal inflammatory response of any stage or grade in patients with positive microbiological findings. No statistically significant difference was found for the maternal inflammatory response of any stage or grade (p=.09), but the difference in the distribution of the fetal inflammatory response of any stage or grade was found to be statistically significant (p=.006). Intensity of the fetal inflammatory response was higher in patients with positive cultures, and there was a statistically significant association between the positive microbiological findings and the stages and grades of fetal inflammatory response.

Conclusion: Positive microbiological findings increase the risk for histopathologically proven acute chorioamnionitis in patients with preterm delivery. In this category of patients there is a significantly higher frequency of acute inflammatory changes of the umbilical cord, with higher frequency of the higher stages and grades of fetal inflammatory response and statistically significant association between the positive culture and the intensity of the fetal inflammatory response.

Key words: microbial invasion, intraamniotic infection, chorioamnionitis, placentitis, funisitis
INTRODUCTION

Preterm delivery is a clinical syndrome with multifactorial etiology and it is considered to be one of the most challenging issues of contemporary perinatology. Estimations of the World Health Organization (WHO) are that each year almost 15 million babies were born before 37th gestational week (g.w) and that complications associated with preterm delivery are responsible for 35% of cases of neonatal and infant mortality [1]. Globally accepted definition of preterm delivery states that every delivery prior to 37th g.w is a preterm delivery. Depending on the gestational age, preterm delivery is divided in three categories: extremely preterm, less than 28 g.w; very preterm, starting from 28th till 32nd g.w, and moderate to late preterm, starting from 32nd till 37th g.w. The group of moderate to late preterm is divided in two sub groups: moderate, from 32nd to 34th g.w, and late, from 34th to 37th week [2].

Multifactorial etiology of the preterm delivery makes it difficult to determine the importance of only one risk factor associated with the evolution of this condition. However, evidence published to date strongly suggest that intrauterine infections play one or the leading roles in the development of this clinical entity, causing inflammatory changes of the placenta, fetal membranes and the umbilical cord. More than one quarter (26%) of the preterm delivered babies, died as a result of infection [3,4]. It is considered that in normal conditions intrauterine environment is sterile. The pathway of intrauterine infection is still not fully understood, but four basic mechanisms have been suggested: ascending infection from the lower genital tract, haematogenous dissemination, unintentional iatrogenic infection during invasive diagnostic and therapeutic procedures (amniocentesis, umbilical cord blood sampling, chorionic biopsy and fetoscopy) and retrograde penetration from the Fallopian tubes. Ascending infection is considered to be the most common mechanism of intraamniotic infection, either by trans cervical invasion of the decidua and consecutive penetration of the multiplied microorganisms in the amniotic cavity, or by direct penetration to the amniotic space via intact fetal membranes [5, 6].

During the 1960s and ‘70s several authors published their results on the association between vaginal infections, preterm delivery and inflammatory changes of the placenta, type chorioamnionitis and placentitis [7,8,9]. Still, more significant advances in this field were registered during the late XX and the beginning of the XXI century. In 1995 Morgan M. and Blanco D.J published the results from 15 studies in which patients with preterm delivery were submitted to amniocentesis for microbiological analysis. They reported a mean rate of positive amniotic fluid culture of 12.2%, varying from 0-48%, depending on the study population and cultivation technique [10]. In the years that followed, vast body of authors, using different techniques for detection of microorganisms, starting from microbiological smear taken from the placental surface and the border between amnion and chorion, amniotic fluid culture and different molecular techniques for isolation of bacterial DNA tried to determine the connection between microbial invasion of the intrauterine compartment, histopathologically proven chorioamnionitis and preterm delivery. Zang M.J and his associates conducted comparative analysis of histological, bacteriological and clinical characteristics of 224 deliveries complicated by infection. They found presence of microbiological pathogens in 49 out of 111 placentas that had histological signs of chorioamnionitis [11].
Using similar sampling technique, microbiological smear from the border between amnion and chorion, Hiller S.L successfully isolated microorganisms in 61% of analyzed samples provided from patients delivered prior to 37th g.w. [12].

The correlation between microbial invasion of the amniotic cavity and acute inflammatory changes of the placenta is not analyzed only through their simultaneous presence, but also through their negative association. In the study of Queires da Mota and al placenta from 367 patients with clear signs of infection of the mother and the newborn were analyzed for microbiological invasion and acute inflammatory changes. Their results showed clear presence of association between acute inflammation of the placenta and bacterial invasion. Even though only 7.4% of cases showed inflammatory changes of the placenta associated with positive microbiological findings, the author concluded that the correlation is indisputable considering the in 61.1% of the cases absence of histopathological changes of the placenta was accompanied by negative microbiological findings [13].

The question is, which mechanism is responsible for the inflammatory changes of the placenta, fetal membranes and the umbilical cord in cases of unproven infection of the amniotic space? It is speculated that one of the possibilities is microbial invasion of the extraamniotic compartment (decidua, placenta and fetal membranes). Other possible mechanism is inflammatory response to noninfectious stimulus such as trauma, ischemia or placental abruption. Whichever the mechanism is, the interaction between intraamniotic bacterial colonization and the inflammatory response could be summarized in 4 fazes: homeostasis, incitation, evolution and resolution. It is considered that some microorganisms, for ex. Ureaplasma urealythicum may exist in utero in small concentration in large number of uncomplicated pregnancies, but as long as the homeostasis is maintained their presence will not induce inflammatory response. In cases of disturbed homeostasis either by invasion of aggressive strains or uncontrolled proliferation of the microorganism, intense inflammatory response is imminent (initiation). This will lead to release of prostaglandins and other inflammatory mediators responsible for initiation of uterine contractions and clinical manifestation of preterm labor (evolution). Once severe intraamniotic inflammation has developed it will almost certainly lead to preterm delivery (resolution). It is not yet clear which factors are responsible for transition from one faze to other, but resolving this issue will probably make a serious impact on our efforts for preservation of the pregnancy and postponing the delivery [14].

**MATERIAL AND METHODS**

We conducted a cross-sectional study at the University clinic for obstetrics and gynecology in Skopje. One hundred and fifty (150) patients with clinical signs of preterm delivery between 24\(^{+0}\)-37\(^{+0}\) g.w. were included with the following inclusion criteria: presence of regular uterine activity (2-5 contractions in 10 minutes) prior to 37\(^{th}\) g.w., cervical dilatation ≥3 cm, cervical shortening of ≤ 20 mm determined by transvaginal ultrasound, spontaneous premature preterm rupture of fetal membranes (pPROM) irrespective of the presence of the above described criteria.
Patients with multiple pregnancy, fetal anomalies, pregnancy induced hypertension, preeclampsia or eclampsia, fetal intrauterine growth restriction, placenta previa or placental abruption were excluded from the study.

For microbiological analysis, samples were taken using standard cotton swab, from the maternal side of the placenta at the border between the placental disk and fetal membranes, following the recommendations of the Perinatal Society of Australia and New Zealand [15,16]. The samples were taken immediately after the expulsion or evacuation of the placenta, placed in a tube with 5 ml of Stuart agar gel transport media, and sent to the Institute of microbiology in Skopje. The samples were cultivated for aerobic and anaerobic flora, Ureaplasma urealyticum/Mycoplasma hominis and Group B Streptococcus, using standard microbiological media.

For histopathologic analysis, placentas were collected in transport container and sent to Institute of pathology. Samples for histopathologic analysis were provided from the following zones: border amnion-chorion, chorionic plate (full thickness section), umbilical cord (cross-section blocks) and fetal membranes (long stripes of extra placental membranes packed in rolls). Analysis of the samples was conducted following Redlines criteria adopted by the Amniotic Fluid Index Nosology Committee of the Perinatal Section of the Society for Pediatric Pathology [17,18]. In the interpretation of the histopathologic findings we used numeric system of grading according to which Stage 0 represents absence of inflammatory changes, Stage 1 represents early inflammatory changes, Stage 2 represents intermediary and Stage 3 advanced inflammatory changes both for the maternal and fetal inflammatory response. Interpretation of the degree of maternal and fetal inflammatory changes was as follows: grade 1- mild to moderate, grade 2- severe and grade 3 – subacute or chronic inflammatory response.

Statistical analysis of the digitalized data was performed using IBM SPSS Statistics for Windows, Version 23.0. Differences in the distribution of the categorical variables was analyzed with Pearson chi square test and Fisher exact test. Differences between ordinary variables were analyzed using Mann-Whitney U test. The results were considered statistically significant if p<.05.

All the subjects included in the study have signed an informed consent form. The study was approved by the Ethical committee for research on human subjects at the Medical faculty, University of “Ss. Cyril and Methodius” - Skopje

RESULTS

Microbiological analysis of provided samples showed a presence of bacteria in 61/150 (40.7%) of the patients. In majority of cases (n=42, 68.9%) microbiological finding was positive for single bacterial microorganism. In 13 patients (21.3%) two different bacterial species were identified, and in 6 patient (9.8%) more than two bacterial species were isolated. Gram positive (G+) facultative anaerobic cocci (Enterococcus, n=24; Staphylococcus coagulase negative Methicillin resistant, n=12) and facultative anaerobic Gram negative (G-) bacilli (Escherichia coli, n=12) were present in majority of cases, although in some cases obligatory anaerobic Gram negative bacilli (Bacteroides fragilis, n=3) and anaerobic Gram positive cocci (Peptococcus, Peptostreptococcus) were found.

Ureaplasma Urealyticum was isolated from 23 samples, as a sole microorganism or in combined presence with other bacteria.
Results from the analysis of the inflammatory changes of the placenta, fetal membranes and umbilical cord, any stage or grade, in patients with positive aerobic/anaerobic culture presented a higher frequency of acute inflammatory changes defined as acute chorioamnionitis, funisitis, umbilical panvasculitis or umbilical vessels thrombosis. Hence, the frequency of maternal end fetal inflammatory response of any stage or grade, was higher in this group of patients, as presented in table 1. Even though the frequency of the inflammatory changes is higher in this group, no statistically significant difference was found for the maternal inflammatory response of any stage or grade (\(X^2=2.95, p=.09\), for \(p<.05\)). On the other hand, the difference in the distribution of the histopathological changes implicating positive fetal inflammatory response of any stage or grade was fond to be statistically significant (\(X^2=7.54, p=.006\), for \(p<.05\)).

**Table 1.** Distribution of maternal and fetal inflammatory response of any stage or grade depending of the results of aerobic/anaerobic cultivation

<table>
<thead>
<tr>
<th>Positive aerobic/anaerobic culture</th>
<th>Maternal inflammatory response</th>
<th>Fetal inflammatory response</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No (n, %)</td>
<td>Yes (n, %)</td>
</tr>
<tr>
<td>No (n, %)</td>
<td>44 (45.8%)</td>
<td>52 (54.2%)</td>
</tr>
<tr>
<td>Yes (n, %)</td>
<td>17 (31.5%)</td>
<td>37 (68.5%)</td>
</tr>
</tbody>
</table>

Further analysis of the intensity of the maternal and fetal inflammatory response, described through different stages and grades, showed statistically significant difference only for the higher grades of the maternal inflammatory response, but not for the different stages (\(X^2=3.64, p=.30\) for \(p<.05\) for the stage, and *Fisher exact p*=.033, for \(p<.05\) for the grade of the maternal inflammatory response). On the other hand, in patients with positive microbiological findings on aerobic/anaerobic culture, the intensity of the fetal inflammatory response was significantly higher than in patients with negative culture, both for the stage and for the grade of the fetal inflammatory response (\(X^2=9.73, p=.02\) for \(p<.05\) for the stage, and *Fisher exact p*=.009, for \(p<.05\) for the grade of the inflammatory response), as presented in table 2.

**Table 2.** Statistical significance of the differences in distribution of the maternal and fetal inflammatory response (any stage or grade) and depending on the stage and grade

<table>
<thead>
<tr>
<th>Positive aerobic/anaerobic culture</th>
<th>Maternal inflammatory response</th>
<th>Fetal inflammatory response</th>
<th>X^2</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Maternal inflammatory response</td>
<td>Fetal inflammatory response</td>
<td>2.95</td>
<td>.09</td>
</tr>
<tr>
<td></td>
<td>Maternal stage</td>
<td></td>
<td>3.64</td>
<td>.30</td>
</tr>
<tr>
<td></td>
<td>Fetal stage</td>
<td></td>
<td>9.73</td>
<td>.02*</td>
</tr>
<tr>
<td></td>
<td>p (Fisher exact test)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maternal grade</td>
<td></td>
<td>.033*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fetal grade</td>
<td></td>
<td>.009*</td>
<td></td>
</tr>
</tbody>
</table>
In order to determine whether the differences detected in the distribution of the different stages and grades of maternal and fetal inflammatory response are dependent on the microbiological findings from the aerobic/anaerobic cultivation i.e. whether there is an association between this variables, we conducted a Mann-Whitney U test. The analysis showed a presence of statistically significant association between the positive aerobic/anaerobic culture and the higher stages and grades of the fetal inflammatory response \((p=.005\) for the stage and \(p=.002\) for the grade). This results confirms that in patients with positive aerobic/anaerobic culture, higher intensity of the fetal inflammatory response is imminent. As for the intensity of the maternal inflammatory response, results showed that there is a statistically significant association between positive aerobic/anaerobic culture and the grade, but not the stage, as presented in table 3.

**Table 3.** Association between microbiological findings on aerobic/anaerobic culture and the intensity of maternal and fetal inflammatory response.

<table>
<thead>
<tr>
<th>Independent variable: positive aerobic/anaerobic culture</th>
<th>(U)</th>
<th>(p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal stage</td>
<td>2143.5</td>
<td>.062</td>
</tr>
<tr>
<td>Maternal grade</td>
<td>2024.5</td>
<td>.015*</td>
</tr>
<tr>
<td>Fetal stage</td>
<td>2073</td>
<td>.005*</td>
</tr>
<tr>
<td>Fetal grade</td>
<td>2033</td>
<td>.002*</td>
</tr>
</tbody>
</table>

\(\dagger\) Mann-Whitney U test

**DISCUSSION**

Results from the microbiological analysis of this study presented a prevalence of microbial invasion of 40.7%. Although this result is lower than the prevalence of microbial invasion reported in some studies published at the end of the last century [19], it is higher than the results that are reported in majority of the studies published in the last 10 years [13,20,21,22]. Taxonomically, most of the bacteria that were cultivated from the samples in our studies, belong to the taxonomic units Firmicutes, Proteobacteria and Tenericutes. According to the results of the recent studies, bacteria that are cultivated from the placenta of patients delivered prior to 37th g.w dominantly belong to the order Actinomycetales and class Alphaproteobacteria. Bacterial taxa that are reported in this study, such as Firmicutes, may originate from the vagina, but the bacteria belonging to the taxonomic units Proteobacteriace are considered to be representatives of the oral cavity microbiota, and together with the bacteria from the genus Tenericutes are described as a part of normal placental microbiota [23,24].
On the other hand, the results from the study published by Theis K.R in 2019 [25], discredited the possibility of the existence of placental microbiota, suggesting that further investigation in this field are necessary in order to determine the significance of different bacterial species in the etiology of preterm delivery and development of the acute inflammatory changes of the placenta in this patients.

Our results presented a statistically significant difference in the distribution of acute inflammatory changes of the umbilical cord (any stage or grade) in patients with positive aerobic/anaerobic culture compared with patients with negative microbiological findings (35.2% versus 15.6%). Furthermore, there was statistically significant difference in the distribution of higher stages and grades of fetal inflammatory response in this group of patients with statistically significant association between the positive aerobic/anaerobic culture and the intensity of the fetal inflammatory response (U=2073, p=.005 for the stage, and U=2003, p=.002 for the grade of fetal inflammatory response). On the other hand the difference in distribution of acute inflammatory changes of the placenta and fetal membrane, as a part of maternal inflammatory response of any stage and grade, between the patients with positive and negative culture were not statistically significant ($X^2=2.95$, $p=.09$), but when the distribution of the different stages and grades of acute inflammatory changes of the placenta and fetal membranes were analyzed, results showed statistically significant difference in the distribution of the higher grades, but not in the distribution of higher stages of maternal inflammatory response between the two groups ($X^2=3.64$, $p=.30$ for the stage, and Fisher exact $p=.033$ for the grade). Analysis of the association between the positive aerobic/anaerobic culture and the intensity of the maternal inflammatory response, also showed significantly higher association between the presence of the bacteria and the grade of the maternal inflammatory response, but failed to show significant association when the stage of the maternal inflammatory response was evaluated ($U=2073$, $p=.062$ for the stage, and $U=2024.5$, $p=.015$ for the grade).

The results of this study confirmed the data that were published so far that the prevalence of the microbial invasion of the placenta is higher in patients with histopathologically proven chorioamnionitis, confirming the statistically significant association between this two variables [13,26,27]. Conformation of our results on the association between the microbial invasion end the intensity of the inflammatory response, that are presented in this study, are found in the results of previously conducted studies which showed that in patients advanced stages of inflammatory response, prevalence of microbial invasion of the intrauterine compartment is significantly higher, compared to patients that presented with intermediate, especially low degree of acute inflammatory response [28].

**CONCLUSION**

Based on the results of this study, we can conclude that positive microbiological findings on aerobic/anaerobic cultivation of the samples from placental surface do not influence the distribution of the acute inflammatory changes of the placenta and fetal membranes (maternal inflammatory response), but the positive association between the positive cultures and the grade of the maternal inflammatory response suggest that in patients with positive microbiological findings, the risk for histopathologically proven acute chorioamnionitis is higher.
This conclusion is confirmed by the fact that in this group of patients there is a significantly higher frequency of acute inflammatory changes of the umbilical cord, with higher frequency of the higher stages and grades of fetal inflammatory response and statistically significant association between the positive findings on aerobic/anaerobic cultivation and intensity of the fetal inflammatory response.

As for the prevalence of the microbial invasion of the placenta, demonstrated by the results in this study, we can conclude that even though our data showed higher rate of microbial invasion than previously reported, there is a need for further investigation pointed towards the determination of significance of specific bacterial taxa and their role in the evolution of the acute inflammatory changes of the placenta, fetal membranes and the umbilical cord.

REFERENCES
Bacterial intrauterine infection and acute inflammatory changes of the placenta, fetal membranes and umbilical cord


ORIGINAL ARTICLE

IMPACT OF EPYSIOTOMY ON ANAL CONTINENCE IN WOMEN AFTER VAGINAL DELIVERY

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ABSTRACT

Aim: The purpose of this study to determine the impact of episiotomy use in women after vaginal delivery on the female anal continence

Methods: The study was designed as a cross-sectional. It was performed at the University Clinic of Obstetrics and Gynecology, University of "Ss. Cyril and Methodius" in Skopje, Macedonia during a period of one year. The study included 470 women of reproductive age with at least 1 previous vaginal delivery. The following variables were analyzed with regard to their influence on anal continence: use of episiotomy, type of episiotomy, perineal injury and degree of perineal injury. Data was acquired using a questionnaire specially designed for this study. The severity of anal incontinence quantified using St. Mark's Anal Incontinence Score.

Results: Both the use of episiotomy and the severity of perineal trauma exerted a significant effect on anal continence. The use of episiotomy has been associated with lower St. Mark’s scores, while higher degrees of perineal trauma, were proven to significantly increase the value of the St. Mark’s score

Conclusion: Anal incontinence is an unsettling condition affecting women that is inextricably linked to vaginal delivery. Further studies are needed to prove the benefit of episiotomy, which is traditionally regarded as a protective procedure and a method for prevention of pelvic floor disorders.

Key words: episiotomy, perineal lacerations, anal incontinence, vaginal delivery, St. Mark's Anal Incontinence Score (SMIS)

INTRODUCTION

The pelvic floor is a complex anatomical structure responsible for maintaining controlled evacuation of urine and feces, but also allows the fetus to pass smoothly through the pelvis and the birth canal during vaginal delivery. Bowel continence is an extremely complex body function that depends on several components: colonic content, nervous and humoral control of intestinal motility, the endo- and exogenous secretory mechanisms, the sensory function of the rectum and the anal canal, and finally the functional status of the pelvic floor muscles [1]. The effect of pregnancy and vaginal birth on continence function for bowel content does however affect mainly the last component mentioned. To date, much research has been focused on sphincter injuries to explain incontinence in parous women based on the implicit assumption that these injuries and their putative risk factors alone explain bowel incontinence after childbirth.
Impact of episiotomy on anal continence in women after vaginal delivery

This hypothesis has been challenged in recent studies that have shown that the vast majority of community-dwelling women with anal incontinence report that symptoms developed after 40 years of age [2] and that the main risk factors were not related to childbirth but instead to diarrhea, IBS, smoking, cholecystectomy and obesity [3]. These observations indicate that the hypothesis of multiple factors is more relevant [4].

Anal incontinence is a condition in which women are affected eight times more often than men, and the reason for this difference is thought to be childbirth [5]. The term Anal Incontinence (AI) includes both fecal and flatal incontinence. Anal incontinence can be subdivided into several components: involuntary leakage of gas, solid, loose or liquid stools, passive leakage of stool (soiling or staining), and urgency incontinence. The terms anal incontinence and fecal incontinence are used some inconsequentially, sometimes even as synonyms in medical texts [6]. Although obstetric anal sphincter injury can cause immediate AI, it is more typical for this condition to begin 2 – 3 decades after vaginal delivery among unselected women [7]. These observations suggest that similar to urinary incontinence, obstetric pelvic floor injury is an important risk factor for postpartum AI.

Anal incontinence as a direct consequence of childbirth is more common than previously believed. The major risk factors are thought to be injury to the anal sphincter during childbirth and subsequent vaginal delivery but many authors in these risk factors often include episiotomy [8]. There are numerous studies in which the need for episiotomy has been investigated as a significant protective factor or as a factor for pelvic floor deterioration and subsequent deterioration of the continence.

Episiotomy or perineotomy, by definition, is a surgical procedure used to expand the exit of the birth canal during vaginal delivery by incising the perineum, starting from the posterior commissure of the vulva towards the perineum. Overall incidence varies widely from 19.4% in the United States to 92.3% in Latin America [9], 79% in France [10] and 97.9% in Hong Kong [11]. Most commonly stated arguments for this widespread use are: protection of the fetal head during the expulsion over the perineum and therefore reducing the perinatal morbidity caused by fetal head compression, reduction of the risk for third and fourth degree perineal tears and protection of the pelvic floor [12]. These arguments became very loose throughout the years, as more and more studies were published, stating that none of these indications can be data confirmed. Still, there is no evidence that we can completely dismiss the use of episiotomy in every day practice, especially when high risk obstetric situations are in question such as: fetal distress, breach presentation, shoulder dystocia and instrumental vaginal delivery (vacuum extraction and forceps).

The procedure was originally introduced by Sir Fielding Ould, in 1742. Depending on the direction of the incision, episiotomy can be medial, mediolateral or lateral. Mediolateral episiotomy is the most commonly used. Lateral episiotomy as well as the medial episiotomy are rarely used, first one because of the increased risk for anal sphincter injuries, and the second because of the increased blood loss due to the injury of the pelvic floor muscles [13]. After the introduction, the procedure was not gladly indorsed until the early XIX century when the era of episiotomy as a routine obstetrical practice began. In years that followed it was a standard procedure in every woman delivering vaginaly. The revolution started in 1983, when a review of 20 years period of time was published.
The main conclusion of the review was that there is no benefit from the procedure and even more that there are serious complications associated, especially when postpartum pain and discomfort are taken into consideration [14]. Further reviews showed that not only episiotomy does not prevent from perineal damage and does not protect for pelvic floor disorders, but also fails to accomplish its purpose in prevention against intrapartum fetal complications such as asphyxia and intracranial hemorrhage [15]. The same review confirmed previously stated concerns about the increase in the short and long term morbidity by increasing the blood loss, larger risk for anal sphincter injuries and prolonged healing period accompanied by pain and discomfort and changes in anal continence as a consequence.

It is difficult to diagnose altered continence and incontinence in most cases. It is mostly based on patient self-reported. There is no objective method for measuring anal incontinence. There are a number of scores to determine the type and frequency of incontinence symptoms. There are also a number of unified questionnaires specific to anal incontinence. The use of incontinence questionnaires has proven to be the best approach for patients, because of questions of such an intimate nature women are not willing to talk freely. Anal incontinence is considered a taboo and is the unvoiced symptom [16].

Nowadays days prevention of pelvic floor dysfunction is reported to be the main cause for requesting caesarean section for non-medical reasons. The very thought of becoming permanently incontinent to feces or gas due to vaginal delivery has been shown to be the primary reason why some women contemplate caesarean section. This trend is also steadily rising and in several studies this attitude was shown to be most prevalent among female physicians [17].

Academic thought is restless. This is precisely the basis of our study, to determine the impact of episiotomy use in women after vaginal delivery on the female anal continence.

**MATERIALS AND METHODS**

The study was designed as a cross-sectional. It was performed at the University Clinic of Obstetrics and Gynecology, University of "Ss. Cyril and Methodius" in Skopje, Macedonia during a period of one year. The study included women of reproductive age with at least 1 previous vaginal delivery, who fulfilled inclusion criteria for the study: one or more vaginal deliveries. Patients who have had previously delivery with caesarean section were included in the study only if they had one or more vaginal births before or after caesarean section completed vaginally. We have excluded from the study patients with anal incontinence from non-obstetric etiology which manifested itself before the first pregnancy. Four hundred and seventy (470) patients consented to participate in the study, all of which signed a written consent prior to engagement.

Data of interest to the study was collected using a questionnaire specially designed for this study. We asked the participants to answer the questions themselves and offered assistance if some of them were unclear. The questionnaire included specific questions about the application of episiotomy, type of episiotomy and the presence of perineal injury as well as the degree of the perineal tear. The degree of incontinence was quantified using St. Mark's Anal Incontinence Score (SMIS), appended to the questionnaire, ranging from 0 (no anal incontinence) to 24 (complete anal incontinence).
STATISTICAL ANALYSIS

Questionnaires’ data was digitally processed and entered in the database. Descriptive summary statistics were presented in table and char form, as appropriate. The influence of the different categorical variables on SMIS was tested using Mann Whitney’s U test and Kruskal Wallis H test. The linear relationship of ordinal or continuous variables with the SMIS was tested using Spearman’s rank order correlation test.

All data processing and statistical analysis was done using IBM SPSS Statistics software package, version 23 (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.). A value of p≤0.05 was considered statistically significant.

RESULTS

Four hundred and seventy (470) patients were included in the study. Although St. Mark’s scoring system enables classification of anal incontinence severity, its drawback as well as those of all the other most commonly used scores, is that there is no consensus on the cut-off value. Since there is no such consensus for quantifying anal incontinence, it was a challenge for us to evaluate anal incontinency. Considering the fact that scientific studies provide evidence that patients with St. Mark’s score of ≥8 experience changes in their quality of life, we used value 8 as cut-off value in classifying patients into 2 groups for the purposes of statistical analysis: group 1 (St. Mark score <8) and group 2 (St. Mark score ≥8).

Of the total number of patients included in the study, 70% had no change in continence, ie. St. Mark's score was <8. 141 patients (30%) had symptoms of incontinence read as increased St. Mark's score was ≥8. The mean value of St. Mark’s score in the group was 5.24, varying from 0 to 18, with SD od 3.44. The results are presented in chart 1.

Chart 1. Distribution of patients according to St. Mark’s score

St. Mark’s score for incontinence includes questions regarding incontinence of the solid stool, gas, liquid stool, alteration in your lifestyle, need for hygienic pads and need to use laxatives.

For the question “Do you have incontinence of solid stool?”, 167 (35.35%) of the participants answered “never”, 156 (33.19%) of the participants answered “rarely” , 133 (28.3%) of the participants answered “sometimes”, 8 (1.7%) answered “weekly” and 6 (1.28%) of the participants answered “every day”.

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For the question “Do you have incontinence of liquid stool?”, 140 (29.79%) of the participants answered “never”, 156 (33.19%) answered “rarely”, 156 (33.19%) answered “sometimes”, 14 (2.98%) answered “weekly”, and 4 (0.85%) of the participants answered “every day”. For the question “Do you have incontinence of gas?”, 91 (19.36%) answered “never”, 139 (29.57%) answered “rarely”, 188 (40%) answered “sometimes”, 38 (8.09%) answered “weekly”, and 4 (0.85%) answered “every day”.

For the question “Do you experience alteration in your lifestyle?”, 249 (52.98%) answered “never”, 74 (15.74%) answered “rarely”, 132 (28.09%) answered “sometimes”, 14 (2.98%) of the participants answered “weekly”. Only 1 of the participants stated that she experiences alterations in her lifestyle on daily basis.

For the question “Do you use hygienic pads?”, 360 (76.6%) answered “No”, while 110 (23.4%) answered “Yes”. For the question “Do you need to use laxatives?”, 416 (88.51%) answered “No”, while 54 (11.49%) answered “Yes”. For the question “Do you feel inability to postpone defecation for more than 15 min.?”, 452 (96.17%) answered “No”, and 18 (3.83%) answered “Yes”.

Table 1 represents the complete summary of the results from the questionnaire used to evaluate the continence status of the patients included in the study.

<table>
<thead>
<tr>
<th>Incontinence for</th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Weekly</th>
<th>Daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid stool, n (%)</td>
<td>167 (35.53%)</td>
<td>156 (33.19%)</td>
<td>133 (28.30%)</td>
<td>8 (1.7%)</td>
<td>6 (1.28%)</td>
</tr>
<tr>
<td>Liquid stool, n (%)</td>
<td>140 (29.79%)</td>
<td>156 (33.19%)</td>
<td>156 (33.19%)</td>
<td>14 (2.98%)</td>
<td>4 (0.85%)</td>
</tr>
<tr>
<td>Gas, n (%)</td>
<td>91 (19.36%)</td>
<td>139 (29.57%)</td>
<td>188 (40%)</td>
<td>38 (8.09%)</td>
<td>14 (2.98%)</td>
</tr>
<tr>
<td>Alteration of lifestyle, n (%)</td>
<td>249 (52.98%)</td>
<td>74 (15.74%)</td>
<td>132 (28.09%)</td>
<td>14 (2.98%)</td>
<td>1</td>
</tr>
<tr>
<td>Need to wear a pad or plug, n (%)</td>
<td>360 (76.6%)</td>
<td>110 (23.4%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Taking constipating medicine, n (%)</td>
<td>416 (88.51%)</td>
<td>54 (11.49%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of ability to defer defecation for 15 min, n (%)</td>
<td>452 (96.17%)</td>
<td>18 (3.83%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Use of episiotomy**

Our primary goal was the use of episiotomy and its effect on the incontinence score value. Most of the women 57.23%, had at least one delivery with a medio-lateral episiotomy- 269 patients. 165 patients (35.11%) had no episiotomies, while 36 patients (7.66%) had a median episiotomy.

Patients with no previous episiotomies had a mean SMIS of 6.21, patients with at least one medio-lateral episiotomy had a mean SMIS of 4.55, while patients with at least one median episiotomy had a mean SMIS of 6.06 (Table 2).
Table 2. Distribution of mean values of SMIS in relation to episiotomy use

<table>
<thead>
<tr>
<th>Use and type of episiotomy*</th>
<th>n (%)</th>
<th>Mean SMIS value</th>
<th>Kruskal-Wallis H test p</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>165 (35.11%)</td>
<td>6.21</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Medio-lateral</td>
<td>269 (57.23%)</td>
<td>4.55</td>
<td></td>
</tr>
<tr>
<td>Medial</td>
<td>36 (7.66%)</td>
<td>6.06</td>
<td></td>
</tr>
</tbody>
</table>

*At least one delivery with an episiotomy

Patients with at least one medio-lateral episiotomy had significantly lower (p<0.001) mean values of SMIS, compared to patients with median episiotomy and patients with no episiotomy.

Obstetrical perineal trauma

The next we examined was the presence and degree of laceration of the perineum. The majority of patients 84.68%, had no perineal trauma (398 patients) Thirty four patients (7.23%) had first degree perineal tears, 21 patients (4.47%) had second degree tears, 16 (3.4%) had third degree tears, while only one patient had a fourth degree perineal tear. Patients with at least one high grade (2nd, 3rd or 4th degree) perineal tear had a mean values for SMIS of 7.81, 9.19 and 15, respectively, while patients with 1st degree perineal tears and patients with no obstetric perineal trauma had mean SMIS values of 5.03 and 4, respectively. The statistical analysis revealed a positive (rho=0.158), statistically significant (p<0.001) correlation between the degree of obstetric perineal trauma and the SMIS value (Table 3).

Table 3. Distribution of mean SMIS values in relation to the degree of obstetric perineal trauma

<table>
<thead>
<tr>
<th>Degree of perineal tear</th>
<th>n (%)</th>
<th>Mean SMIS value</th>
<th>rho*</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>398 (84.68%)</td>
<td>5.03</td>
<td>0.158</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Grade I</td>
<td>34 (7.23%)</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade II</td>
<td>21 (4.47%)</td>
<td>7.81</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade III</td>
<td>16 (3.4%)</td>
<td>9.19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade IV</td>
<td>1 (0.22%)</td>
<td>15</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Spearman rank-order correlation

Both factors examined had a significant effect on the score. The presence of episiotomy has been shown to be a factor leading to lower scores. And the presence of higher levels of perineal lacerations has proven to be a factor that significantly increase the value of the St. mark’s score.

DISCUSSION

Anal incontinence is not a condition encountered seldom, however the exact incidence rate of anal incontinence is largely unknown. Incidence rates vary in different studies, probably owing to the difference in definition and/or inclusion and exclusion criteria in the studies. It is thought that the most common cause of anal incontinence in the female population is obstetric injury during vaginal delivery.
The ultimate goal of epidemiological research is the prevention of disease. If this principle is applied to the present study then the goal is to obtain information leading to the prevention of the unwanted consequences of childbirth on pelvic floor function. Such information would not only be useful to guide the evidence-based practice of doctors involved in delivery care but also provide useful information for women in their decision-making with regard to mode of delivery.

Episiotomy has been and still is a strategy for the prevention of fetal trauma, but also for prevention of maternal perineal trauma, which has been used for a hundred years. It is defined as deliberate incision of the perineum in order to protect the mother of the infant from injury to the anal sphincter or to shorten the second stage of labor. There are several types of episiotomies, and difference between the episiotomies is actually in the cutting angle [18]. Unfortunately, often the types of episiotomy are not defined or used equally. Medial episiotomy increases the risk of obstructive anal sphincter injury [19]. The medial episiotomy is used in America, and the medial and lateral in European countries [20]. European studies indicate a protective effect on mediolateral episiotomies, especially between primiparous woman and in deliveries where vacuum extractor of forceps are used [21]. The suture angle of the mediolateral episiotomy after delivery is 15–20 degrees lower than the incision angle, which is the result of perineal distension during fetal head delivery [22]. The incision angle should be large enough to achieve the protective effect of mediolateral episiotomy [23]. The use of episiotomy has decreased significantly over the last decades, from 60% in 1979 to 24% in 2004 in the United States and from 20% to 7% in some Scandinavian countries [24].

Episiotomy is a surgical procedure in which the incision is necessary to be sutured. It has potential complications, which include bleeding and infections and should therefore be used when indicated and not routinely [25]. This conclusion is also confirmed by the Cochrane Database, based on randomized controlled trials comparing the restrictive and routine use of mediolateral episiotomy [26]. The frequency of restrictive episiotomy (8–57%) and routine episiotomy (47–100%) overlap and vary widely between studies, making the results difficult to compare. It is important to note that none of these studies compared the effect of episiotomy versus no use of episiotomy. Only selective indication use was compared with routine use of episiotomy [27]. Noteworthy is a study from Australia in which the risk of anal sphincter injury was reduced by 50% when episiotomy use increased from 12% to 20% over a 5-year period [28]. A Norwegian study of 424,000 patients also confirmed that a high percentage of episiotomy use had a protective effect on anal sphincter injury and onset of anal incontinence as a consequence [29].

According to the results obtained in our study, use of episiotomy statistically significantly reduces the risk of anal incontinence (OR = 0.32, 95% CI 0.15-0.71). Of the total number of subjects, mediolateral episiotomy was performed in 67 (82.7%) patients and all of them had St. Mark’s score < 8 Therefore, according to our study the use of episiotomy has been shown to be a visible protective factor.

Addressing the question of episiotomy and increased risk for obstetric anal sphincter injuries (OASIS), a study group from Norway conducted a case-control study in order to investigate the correlation between the geometrical characteristics of the episiotomy and OASIS [9].
The data confirmed their suspicion that the angle, length, depth as well as the incision point is a factor influencing the potential risk for OASIS when episiotomy is performed. More precisely, to large or to small angle of the incision (< 15 and > 60 degrees) were associated with anal sphincter injuries, recommending that the ideal angle ranges between 30 and 60 degrees. In 2013 a population-based registry study was done on 384,638 patients, aiming to evaluate the association between lateral episiotomy and OASIS [30]. They observed positive association between episiotomy and OASIS, leading to the conclusion that the procedure offers no protection, especially in women with high risk. The study confirmed the conclusions from the Norwegian group study, that the risk for OASIS increases depending of the incision point, length and depth.

Contrary to the results of these two studies, a prospective cohort study which included 451 patients who had at least one vaginal delivery was conducted [31]. The aim was to investigate the relationship between episiotomy, perineal lacerations, operative vaginal delivery, and pelvic floor disorders. Twenty eight percent of the participants had at least one operative delivery, 61% had at least one delivery with episiotomy and 35% had one or more than one vaginal delivery “complicated” with perineal laceration. Surprisingly, the risk for prolapse was significantly higher in women with one or more perineal lacerations. Authors suggested that, according to the recent magnetic resonance imaging studies, avulsion of the levator ani muscle from its attachment to the pubic bone plays an important role in the mechanism of pelvic organ prolapse. Increased incidence of this condition in above mentioned group could be explained by excessive stretching of the muscle during crowning of fetal head. As far as the anal incontinence is concerned, the study did not show increase of its prevalence in episiotomy group, although a positive association between episiotomy and OASIS was recorded.

According to results collected in our study, the obstetrical perineal injuries of third and fourth degree are one of the most significant risk factors for anal incontinence. The patients with 2nd, 3rd or 4th degree perineal tears had average SMIS values of 7.81, 9.19 and 15, respectively, while patients with no perineal tear and 1st grade perineal tears had SMIS values of 5.03 and 4, respectively. The analysis identified a positive and statistically significant correlation between the degree of obstetric perineal trauma and SMIS (rho=0.158, p<.001), confirming the hypothesis that higher degree of perineal tears, higher the risk for anal incontinence.

CONCLUSION

Anal incontinence is an unsettling condition affecting women usually later in life, but not seldom during their reproductive period. Regardless of the traditional use of episiotomy as a protective procedure and a method for prevention of pelvic floor disorders, there is certain disagreement on the role of episiotomy for prevention of pelvic organ prolapse and anal incontinence. Further studies are needed to prove the benefit of episiotomy but also to determine whether additional factors, such as the experience of a physician and a midwife, are influenced by obstructive tarsus and subsequent symptoms of anal incontinence.

First and second degree perineal tears must not be seen as failure. Training of the midwifery stuff and obstetrics residents should be conducted on techniques for perineal protection during uncomplicated vaginal delivery.
However, episiotomy should still remain a valuable tool in circumstances of complicated vaginal delivery. Obstetricians should pay more attention to possible symptoms of anal incontinence after childbirth in order to develop appropriate delivery plan in future pregnancies. Despite the existing recommendations for restrictive approach to the use of episiotomy, obstetricians should be aware of the appropriate use of episiotomy can prevent perineal tears of higher degree (grade 3 and 4), which have been proved to be highly associated with development of anal incontinence. Having this in mind, mediolateral episiotomy is recommended. Patients who have had anal sphincter injury and subsequent anal incontinence at the time of first vaginal delivery due to the proven worsening incontinence symptoms at each subsequent vaginal birth cesarean delivery should be considered as an alternative.

REFERENCES:
CASE REPORT

EMERGENCY PATCH REPAIR OF POSTERIOR LEFT VENTRICLE WALL RUPTURE

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²The Royal Wolverhampton NHS Trust

ABSTRACT

Introduction: Left ventricular wall rupture is a very rare condition. There are few publications of deliberate needle injuries in context of physical violence or self-inflicting harm in the context of major psychiatric disorders. Objective: Exposing the complexity of treatment of left ventricular wall rupture and care involved in the treatment.

Case report: Case presentation of a 32-year-old intravenous drug user who presented with shock at the emergency department in Russell’s Hall Hospital on 8th of July 2019. The patient had a background of needle fracture during iv drug injection that resulted in needle mobilisation to the pulmonary circulation two months ago. Immediate diagnosis of cardiac tamponade resulted in drainage of fresh blood. On admission the patient still had the drain in the pericardium with 700 ml of blood drained since insertion. Treatment was undertaken with emergency sternotomy. Lifting the heart showed defect in the muscle of the posterior wall of the left ventricle, supplied by the large obtuse marginal artery deriving from the left circumflex coronary artery. The size of the defect was 4 x 1.5 cm and did not appear transmural. The first attempt for patching the defect was done on beating heart. The defect was covered with Tacho-Seal and Exo-cel glue and Cardio-Cel patch. The mattress sutures were then tied taking care not to cut any muscle.

Conclusion: Spontaneous heart injuries are very rare conditions. Full functionality of the health system is essential in every segment for treating these patients. Expertise and awareness are decisive in surgical intervention as definitive resolution of this condition.

INTRODUCTION

Foreign bodies in the heart, as a cause of life-threatening conditions, are considered rare in common clinical practise, but recently more and more cases have been published [1-5]. Usually, needles and pins are accidentally inserted by iv drug abusers [6]. There are few publications of deliberate needle injuries in context of physical violence or self-inflicting harm in the context of major psychiatric disorders [7, 8]. Even, paediatric cases have not been spared [9,10]. Left ventricular wall rupture is a very rare condition. We present a case of a life-threatening condition caused by accidental needle insertion with a consecutive heart tamponade and ventricular wall rupture requiring a quick intervention in a multifunctional health service system.

CASE PRESENTATION

A 32-year-old intravenous drug user presented with shock at the emergency department in Russell’s Hall Hospital on 8th of July 2019. The patient had a background of needle fracture during iv drug injection that resulted in needle mobilisation to the pulmonary circulation two months ago. Immediate diagnosis of cardiac tamponade resulted in drainage of fresh blood. The patient was transferred to New Cross Hospital Heart and Lung Centre. At admission the patient still had the drain in the pericardium with 700 ml of blood drained since insertion.
Systolic arterial blood pressure was 90 mmHg and the patient was peripherally cold. Chest x-ray showed a visible needle behind the heart shadow, most likely in the left lower lobe.

Treatment was undertaken with emergency sternotomy. Around 500 ml of fresh blood was still present in the pericardium. Lifting the heart showed a defect in the muscle of the posterior wall of the left ventricle, supplied by the large obtuse marginal artery deriving from the left circumflex coronary artery (Figure 1).

The size of the defect was 4 x 1.5 cm and did not appear transmural. The first attempt for patching the defect was done on beating heart. The needle was removed (Figure 2) and measured (Figure 3). Due to the unsatisfactory result, the repair was continued with cardiopulmonary bypass: the heart was elevated and seven horizontal mattress sutures with Cardio cel pledgets were placed around the defect.
The defect was then covered with Tacho-Seal and Exocel glue (Figure 4.) Onto this, Cardio-Cel patch was parachuted. This was quite large with about 1.5 cm margin around the defect. The mattress sutures were then tied taking care not to cut any muscle. Finally the whole patch was covered again with Tacho-Seal larger than the pericardial patch. This all gave a good technical result.

**DISCUSSION**

Needles that have entered the body through the veins usually end in the lungs. The penetration in the heart leads to injuries followed by haemothorax, pneumothorax or even tamponade. Usually the first symptoms are chest pain [11], dyspnœa [12], but in some cases symptoms appear after a longer period and the cause is discovered later [13]. In our case report the symptoms in the young man occurred one month after the needle penetration. Still, at the moment of the referral to the institution, the situation was life-threatening. Usually the foreign bodies in the heart are being explored by minimally invasive procedures [14-16]. But, determination of the exact location and needle extractions often need highly invasive procedures, sternotomy and open heart surgery [1]. The presented case shows the need of a quick fully operational medical system with short time for diagnosis, procedure of removal and patients recovery.

**CONCLUSION**

Spontaneous heart injuries are very rare conditions. Full functionality of the health system is essential in every segment for treating these patients. Expertise and awareness are decisive in surgical intervention as definitive resolution of this condition.

**REFERENCES**

CASE REPORT

OPEN ACCESS HERNIOPLASTY IN SUPRAPUBIC INCISIONAL HERNIA-
CASE REPORT

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ABSTRACT

Introduction: Suprapubic incisional hernia are midline peripheral ventral hernias located within 5 cm of the pubic arch. Most frequently it can occur after gynaecologic surgery procedures. Repair of this type of hernia is still challenging for the surgeons, because it is difficult to fix meshes at the desired position and to achieve adequate overlapping of the defect. This paper will show the case of a patient with suprapubic incisional hernia who has been successfully operated with open access hernioplasty by placing an intraperitoneal composite mesh (IPOM- intraperitoneal onlay mesh).

Case presentation: A 66-year-old female patient, with a history of previous hysterectomy performed with lower midline incision laparotomy and clinically verified suprapubic incisional hernia with the size of a child’s head. CT scan confirmed the incisional hernia defect stretching from the pubic symphysis up to 5 cm below the navel, across all layers of the abdominal wall and it has 2/3 of the small intestine and the sigmoid colon present as a content inside the hernia sac. Open hernia surgical repair was performed and during the operation hernia defect of 9 x 8 cm was measured and according to that an intraperitoneal composite mesh (Parietex-polyester mesh with absorbent collagen film) with dimensions 30 x 20cm was placed. Inferiorly, the mesh was fixed to the Cooper’s ligaments and the pubic bone with non-absorbable tackers. The rest of the mesh was fixed with transfascial sutures through the abdominal muscles.

Discussion: After hospital discharge, the patient was followed up during a period of 21 months. In the early postoperative period, postoperative complications such as seroma, hematoma, SSI (surgical site infections), complications related to the mesh (infection, fistula) were not reported. Also, no clinical signs of recurrence were noticed.

Conclusion: The decision for the surgical treatment of complex suprapubic hernias is still a challenge for the surgeons. Individual approach leads to successful operative treatment. There is still need of randomized controlled trials to be undertaken, as well as reaching consensus guidelines regarding the ideal method of hernioplasty in the patients with suprapubic incisional hernias.

Keywords: suprapubic incisional hernia (SIH), intraperitoneal composite mesh, IPOM technique.

INTRODUCTION

Suprapubic incisional hernias were first described by El Mairy in 1974. [1]. These hernias are defined as ventral hernias, located peripherally to the midline up to 5 cm from the pubic arch [2]. They can occur after numerous surgeries, especially after gynaecological interventions (caesarean section, ovarian interventions, total or partial hysterectomy) [3-6]. These hernias can be found in the literature as "suprapubic" or "parapubic" incisional hernias. [4-7].
The prevalence of SIH after Pfannenstiel incision is very low and varies from 0.5 to 2.1% [7,8], compared with incidence of incisional hernia following lower median incision ranging from 12.8% in meta-analyses to 69% in high-risk patients in prospective studies [9]. The Pfannenstiel incision has other advantages over the medial incision, which is a lower percentage of wound infections, hematomas, postoperative pain and aesthetic appearance [8].

In the literature, the occurrence of this type of hernias is rare, so there is little information about clinical features and surgical treatment. The challenge for the surgeon in repairing this type of hernia is in the process of fixing the grid and adequately covering the defect, given that in this section important anatomical structures, such as the bladder, iliac blood vessels, etc are present. The abdominal muscles that are repaired are attached to the pubic arch in the inferior part, while the mesh should be fixed to the Cooper's ligament during placement, which is the most difficult part in setting and fixing the mesh. Which method and approach is going to be used is still challenging, because there are not enough studies yet to compare the laparoscopic and open access of hernioplasty in this type of hernia.

Repairing SIH is still challenging, because of the higher pressure at the lower abdominal wall in erect position and greater chance of relapse after repairing.

This paper will represent a case of a patient with suprapubic incisional hernia, who was successfully operated with open access hernioplasty by placing intraperitoneal composite mesh.

CASE PRESENTATION

Patient

A 66-year-old female patient who was admitted to a surgical outpatient clinic, because of swelling in the suprapubic region with occasional pain, will be presented in this case. The patient is obese, with BMI-32, with history of previous hysterectomy performed with lower medial laparotomy three years ago and receiving regular treatment for hypertension. The patient reported that she had been examined by a surgeon three times before and that she had been instructed to wear a support band for lower abdominal hernia. As hernia is a cosmetic problem and an obstacle to performing the patient's daily activities, there is an indication for surgical treatment. Clinical examination of the patient reveals a protrusion in the suprapubic region, with size of a child's head and mild palpation pain (Figure 1, A,B). A CT scan verifies a tendon defect that extends from the pubic symphysis through all layers, up to 5 cm below the navel, and contains 2/3 of the small intestine and sigmoid colon. With a diagnosis of suprapubic incisional hernia, an indication was given for operative hernia treatment and the patient was referred for appropriate preoperative examinations (hematologic status analysis, electrolytes, degradation products, blood sugar level, protein status, CRP and blood group determination; haemostasis tests, chest x-ray, ECG). At the anaesthesiological examination the patient was assessed with ASA 2 (a scoring system for assessing the clinical and physiological status of the patient with the aim of adjusting the type and dose of anaesthetics and to enable safe surgery, established by the American Society of Anaesthesiologists. In this case ASA-2 patient with mild systemic disease).

Surgical technique

During the entire perioperative process, all recommendations and principles for safe surgery were implemented in the patient, guided by the WHO's operative checklist for safe surgery, introduced by the Ministry of Health of the Republic of Macedonia. Preoperatively, a single dose of a third-generation cephalosporin antibiotic is administered one hour before the procedure. Also a Folley catheter was inserted into the bladder, just before the start of operation. The patient was placed in the supine position and the intervention was done in general anaesthesia.
The incision was made through a previous cicatrix (lower medial laparotomy), with a previous excision of cicatrix. The bladder was mobilized and a retropubic space (Retzius space) was opened in order to expose the Cooper ligaments and pubic symphysis and to create enough space for mesh fixation[10]. The hernia sac was opened and we started with sharp adhesiolysis of the intra-intestinal adhesions. 2/3 of the pouch was removed. A defect 9 cm long and 8 cm wide was measured. According to the guidelines for the surgical treatment of ventral hernias (recommendations of the European Hernia Association, EHS), the prosthetic mesh should be 5 cm larger than the measured defect (overlap). In this case an intraperitoneal composite web (Parietex- polyester mesh with absorbent collagen film with rectangular shape) of 30 x 20 cm was used [11]. At the bottom mesh was fixed to the Cooper's ligaments and the posterior part of the pubic bone with non-absorbing tuckers (Figures 2 and 3). The rest of the mesh was fixed with ten transfascialsutures (non-absorbent monofilament 0 prolene sutures) using a Reverdin needle (Figure 4).

Fig. 1. Suprapubic incisional hernia, A: frontal view, B: profile view.

Fig 2. Mesh fixation

Fig 3. Mesh fixation
Then, the excess skin was removed and the operative wound was closed. Postoperatively, the patient was administered an antibiotic (third generation cephalosporin), NSAIDs and low molecular weight heparin. On the day of surgery, according to the VAS (Visual Analogue Scale to measure the degree of pain) the patient rated the pain 8/10, and during the following postoperative days the pain was rated 3/10. The patient was discharged on the seventh postoperative day, in good general condition and good looking surgical wound, with recommendation for normal activity, use of oral analgesics as needed and to avoid lifting of heavy things. The first check-up was on the fourteenth postoperative day, with orderly local finding (Figure 5).
DISCUSSION

Suprapubic incisional hernias have also been described as "atypical incisional hernias", and some authors claim that they should be considered a separate entity unlike other incisional hernias [12, 13]. These hernias are a challenge for the surgeon, because of the proximity of the bone structures, achieving adequate defect coverage with the mesh and proper mesh fixation [13, 14].

Special attention should also be given to the preoperative evaluation of the patient. Due to the specificity of this type of hernia and the lack of consensus regarding treatment, each patient should be evaluated individually and the plan of surgery should be made according to the individual characteristics. Particularly important in patient history is obtaining detailed information about previous surgical interventions in the lower anterior abdominal wall. A physical examination should attempt to assess the lower edge of the hernia and its relation to the pubic symphysis. Radiological examinations, primarily computed tomography (CT), which can identify the borders of the defect, the contents of the sac, and the relation of hernia with pubic symphysis are also important.

In our case, the patient preoperatively had an objective evaluation of the hernia defect, and the contents of the hernia sac, had a good pre-operative evaluation of the overall health condition, which facilitated the whole process of surgical treatment in the patient. Post-operatively a satisfactory cosmetic effect was achieved in the patient. The follow-up of the patient lasted for 21 months. During the early postoperative period, the patient returned to her daily activities three weeks after the surgery without any problems or complications. In the early postoperative period no postoperative complications such as seroma, hematoma, SSI (infections in the area of the operative wound), mesh-related complications (infection, fistula, etc.) were noted.

The recurrence of hernia is not noted until the day of writing this report.

CONCLUSION

The decision for surgical treatment of complex suprapubic hernias is still a challenge for surgeons.

In such cases, individualized approach, detailed preoperative evaluation and investigations lead to successful operative treatment.

In this particular case, the hernioplasty method which was used provided a good cosmetic effect and patient satisfaction, no early postoperative complications were noted and there was no recurrence in the 21-month postoperative follow-up.

The literature still lacks randomized controlled trials of patients with SIH, as well as reaching consensus and guidance as to what would be the best approach and best hernioplasty method in suprapubic incisional hernias.

REFERENCES

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